This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents *will not* correct images, please do not report the images to the Image Problem Mailbox.

THIS PAGE BLANK (USPTO)

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
13 September 2001 (13.09.2001)

PCT

(10) International Publication Number
WO 01/66021 A1

(51) International Patent Classification[7]: A61B 17/14, 17/15, 17/56, 17/90

(21) International Application Number: PCT/AU01/00258

(22) International Filing Date: 9 March 2001 (09.03.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

PQ 6161	10 March 2000 (10.03.2000)	AU
PQ 8999	25 July 2000 (25.07.2000)	AU
PQ 9044	27 July 2000 (27.07.2000)	AU
PQ 9045	27 July 2000 (27.07.2000)	AU

(71) Applicant *(for all designated States except US)*: SMITH & NEPHEW, INC [US/US]; 1450 Brooks Road, Memphis, TN 38116 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: PINCZEWSKI, Leo, Arieh [AU/AU]; 286 Pacific Highway, Sydney, New South Wales 2065 (AU). PARKER, Stephen, John [AU/AU]; 54 Holt Avenue, Mosman, New South Wales 2088 (AU).

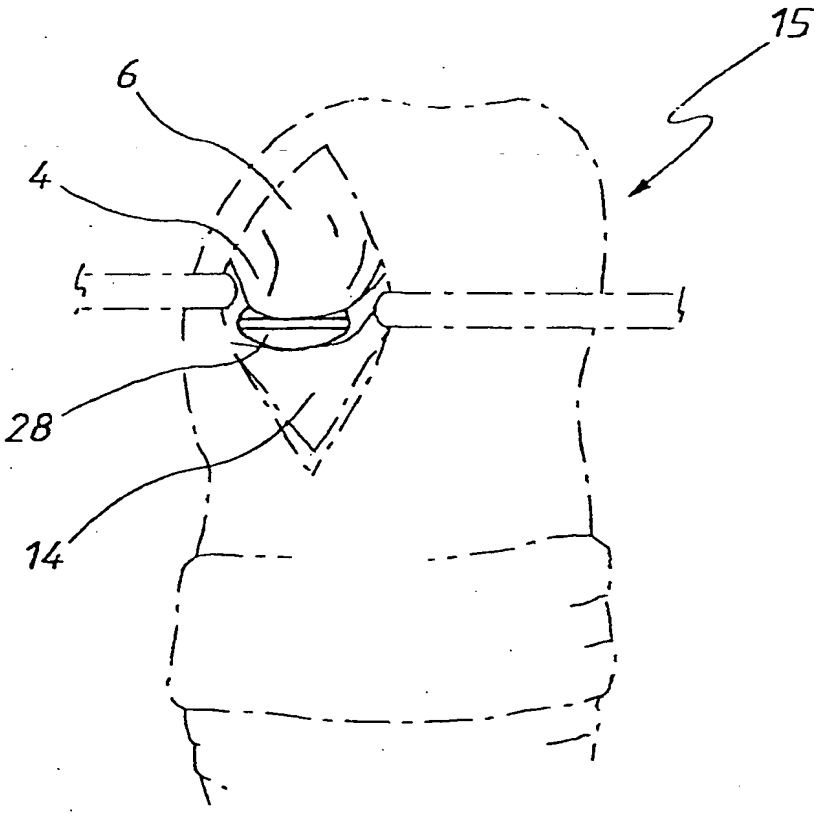
(74) Agent: GRIFFITH HACK; Level 3, 509 St Kilda Road, Melbourne, Victoria 3004 (AU).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian

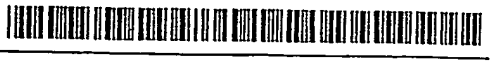
[Continued on next page]

(54) Title: A METHOD OF ARTHROPLASTY ON A KNEE JOINT AND APPARATUS FOR USE IN SAME



(57) Abstract: A method of, and apparatus for, arthroplasty of a knee joint comprising obtaining a desired spacing of the femur (6) from the tibia (14) by inserting a spacer (28) into the knee joint between the femur (6) and the tibia (14). The spacer (28) is used as a reference for securing a guide jig in position about the knee joint for guiding resection of one or both of the femur (6) and tibia (14) for fitting of tibial and/or femoral prostheses. A method of resecting the femur while moving the tibia through an arc of motion to remove bone to the desired depth, a method of determining the position of the guide jig, the guide jig, an alignment device and the spacer are also described.

WO 01/66021 A1



patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Published:

— *with international search report*

ISDOCID: <WO___0166021A1_I_>

A METHOD OF ARTHROPLASTLY ON A KNEE JOINT AND APPARATUS FOR USE IN SAME

Field Of The Invention

The present invention relates to a method of arthroplasty on a knee joint of a patient. The method extends to both unicondylar knee arthroplasty and knee joint arthroplasty involving resection of both the lateral and medial condyles of the tibia and femur. There is also provided apparatus for use in the method.

Background Of The Invention

Various methods and apparatus for performing knee arthroplasty and unicondylar knee arthroplasty in particular, are known in the art. The known methods involve resection of the tibia and femur for fitting of trial tibial and femoral implants, respectively. Once the bone has been resected and the trial implants are secured in place, the surgeon then assesses the kinematics of the knee joint. At this stage, the surgeon may transect, elevate and/or release ligaments and other soft tissue structures to achieve the desired level of deformity correction, balance in the tension of relevant ones of the ligaments and other stabilising soft tissue structures, and an acceptable range of motion of the knee joint. Additional bone resection may also be required to achieve the desired outcome. This leads to an increase in operation time with an associated increase in the risk of surgery related complications. Moreover, such additional surgical intervention following fitting of the trial implants potentially leads to subsequent increased discomfort for the patient and increased healing times. Methods and apparatus for use in arthroplasty of a knee joint are exemplified in United States Patent No. 5,171,244 and United States Patent No. 5,520,695.

Summary Of The Invention

It is an aim of the present invention to ameliorate one or more problems of the prior art or at least provide an alternative to the prior art.

In one aspect of the invention there is provided a method of arthroplasty on a knee joint, comprising the steps of:

(a) obtaining a desired spacing of the femur from the tibia;

(b) determining depth of bone to be resected from at least one of the tibia and the femur on the basis of the desired spacing of the femur from the tibia to enable fitting of at least one prosthesis selected from tibial and femoral prostheses;

(c) resecting bone from one or both of the tibia and the femur substantially to the determined depth in the or each one, respectively; and

(d) fitting the or each said prosthesis.

The method is particularly suitable for use in unicondylar knee arthroplasty but may also be used in bicondylar knee arthroplasty involving resection of the lateral and medial condyles of both the tibia and the femur. By unicondylar knee arthroplasty is meant arthroplasty involving resection of either the lateral or medial condyles of the tibia and the femur.

The resection of the bone may comprise cutting at least one of the tibia and the femur substantially at the appropriate determined depth in the or each one of the tibia and the femur to remove a segment of bone from the or each one.

Preferably, the resection of the bone from the tibia may comprise forming a recess in the uppermost end of the tibia adjacent to the femur for receiving the tibial prosthesis.

Accordingly, in another aspect of the present invention there is provided a method of arthroplasty on a knee joint, comprising the steps of:

(a) surgically providing access to the knee joint;

(b) obtaining a desired spacing of the femur from the tibia;

(c) determining depth of bone to be resected from an end of the tibia to form a recess for receiving a tibial prosthesis on the basis of the desired spacing of the femur from the tibia;

(d) resecting the bone from the tibia to the determined depth to form the recess; and

(e) positioning the tibial prosthesis in the recess.

The method may further comprise locating a guide jig in position about the knee joint for guiding the resection of the bone. Preferably, the guide jig will be adapted for guiding movement of a cutter device relative to the tibia for shaping the recess to a desired profile. Most preferably, the jig will incorporate a template for guiding the movement of the cutter device relative to the tibia.

Preferably, bone will be resected from both the tibia and the femur to enable the fitting of both the tibial and the femoral prostheses.

Preferably, the desired spacing of the femur from the tibia will be obtained using at least one spacer inserted into the knee joint between the femur and the tibia to thereby provide the spacing.

In unicondylar knee arthroplasty only a single spacer will usually be used to obtain the desired spacing of the femur from the tibia. In contrast, in bicondylar knee arthroplasty a pair of spacers will usually be utilised, one being located between each of

the lateral and medial condyles of the femur and the tibia, respectively. In this instance, the spacers may have the same thickness or a different thickness to each other.

Most preferably, the or each spacer will be adapted for being positioned between corresponding ones of the condyles of the femur and the tibia.

In another aspect of the present invention there is provided a method of arthroplasty on a knee joint, comprising the steps of:

(a) surgically providing access to the knee joint;

(b) selecting at least one spacer for providing desired spacing of the femur from the tibia;

(c) positioning the selected spacer in the knee joint to obtain the desired spacing of the femur from the tibia;

(d) using the spacer as a reference to determine a location on each one of the tibia and the femur indicating depth of bone to be resected from each for fitting of chosen tibial and femoral prostheses;

(e) cutting the tibia and the femur substantially at the determined location on each for resection of the bone from each one to the required said depth; and

(f) fitting the chosen tibial and the femoral prostheses.

Typically, the knee joint will be placed in a position of flexion whereby the tibia is arranged at an angle with respect to the femur for the resection of the bone. Generally, bone will be resected from a posterior side of the femur and the uppermost end of the tibia.

Preferably, a method of the invention will comprise selecting the at least one spacer from a range of spacers for providing different spacings of the femur from the tibia. Accordingly, the selecting of the or each spacer may comprise;

(i) choosing the spacer from a range of spacers for providing a different spacing of the femur from the tibia, respectively; and

(ii) moving the tibia about the femur through an arc of motion between backward and forward positions to evaluate movement of the knee joint while the chosen spacer is in position in the knee joint between the femur and the tibia.

The selecting may further comprise repeating steps (i) and (ii) as necessary to obtain the desired spacing of the femur from the tibia using a different spacer chosen from the range of spacers each time.

The selected spacer will usually be of a thickness for providing appropriate tension and optimising balance in the action of various ligaments and other soft tissue structures of the knee joint during the movement of the tibia about the femur. Preferably, the tension in the knee joint obtained by the spacing of the femur from the tibia with the use of the selected spacer will be substantially retained upon the fitting of the or each prosthesis.

Preferably, the guide jig will be adapted for guiding resection of bone from each of the tibia and the femur. The securing of the guide jig may comprise arranging the jig with the spacer to facilitate the positioning of the jig about the knee joint.

Knowing the relevant dimensions of the chosen tibial and femoral prostheses allows the guide jig to be adapted such that when arranged with the spacer, the guide jig is positioned relative to the tibia and the femur for guiding the cutting of the one or both of them at the depth in the resection of bone therefrom for accommodating the tibial and femoral prostheses. Accordingly, the selected spacer has two roles in unicondylar knee arthroplasty, firstly to space the femur from the tibia and secondly, to act as a reference for resection of bone from one or both of the tibia and the femur to the correct depth.

Therefore, in a further aspect of the invention there is provided a method of determining the position of a guide jig about a knee joint for subsequently guiding resection of one or both of the tibia and the femur to a desired depth in the or each one, respectively, the method comprising:

(a) locating a selected spacer in the knee joint to obtain a desired spacing of the femur from the tibia; and

(b) arranging the guide jig and the spacer together to thereby determine the position of the guide jig for guiding the resection of the one or both of the tibia and the femur.

In addition, a combination approach for resecting bone from the femur to the desired depth may be employed. This may involve resecting a segment of bone from the femur to the desired depth in that bone utilising a guide jig as herein described, and inserting an appropriate cutter device into the knee joint between the tibia and the femur in the absence of the guide jig, for resecting bone from the femur with operation of the device and upon movement of the tibia in an arc of motion about the femur to thereby resect further bone from the femur to the desired depth in that bone for fitting of a femoral prosthesis. If desired, only the latter one of those steps may be employed in the resection of the bone from the femur.

Accordingly, in another aspect of the present invention there is provided a method of arthroplasty on a knee joint, comprising the steps of locating a cutter device in position in the knee joint between the tibia and the femur, and moving the tibia through an arc of motion about the femur between backward and forward positions while the cutting device is being operated and is in position between the tibia and the femur, to

INSDOCID: <WO 0166021A1 I >

thereby remove bone substantially to a desired depth from the femur in a direction of travel of the tibia relative to the femur.

There is also provided apparatus for use in the methods of the invention. Apparatus as described herein may be provided in kit form or as an assembled arrangement.

Hence, in a still further aspect of the present invention there is provided apparatus for use in a method of arthroplasty on a knee joint of a patient, comprising:

a guide jig for guiding cutting of at least one of the tibia and the femur in resection of bone therefrom for enabling fitting of one or both of a tibial and a femoral prosthesis, wherein the guide jig is adapted for being arranged with at least one selected spacer for spacing the femur from the tibia, and for being secured about the knee joint in a position determined by the spacer to guide cutting of the at least one of the tibia and the femur substantially at a desired depth in the or each one, respectively.

Typically, the guide jig will be adapted for guiding cutting of the tibia at a fixed predetermined distance below the spacer. Preferably, the guide jig will be adapted for guiding cutting of both the tibia and the femur when the guide jig is secured about the knee joint in said position.

Accordingly, in yet another aspect of the invention there is provided apparatus for use in a method of arthroplasty on a knee joint of a patient, comprising:

a guide jig for guiding cutting of the tibia and the femur in resection of bone therefrom for enabling fitting of chosen tibial and femoral prostheses, and being adapted for being secured about the knee joint in a position determined by at least one spacer for providing a desired spacing of the femur from the tibia, to guide the cutting of the tibia and the femur at a desired depth in each one, respectively.

In still another aspect of the invention there is provided apparatus for use in a method of arthroplasty on a knee joint of a patient, comprising:

(a) at least one spacer having a predetermined thickness for providing a desired spacing of the femur from the tibia; and

(b) at least one guide jig for guiding cutting of the tibia and the femur for resection of bone to a desired depth from the or each one respectively, to enable fitting of chosen tibial and femoral prostheses;

wherein the guide jig is adapted for being secured about the knee joint in a position determined by the spacer to guide the cutting of the or each one of tibia and the femur substantially at the desired depth in the or each one.

The spacer will normally be provided as one of a set of spacers for providing different spacings of the femur from the tibia respectively, thereby allowing the selection of different ones of the spacers as needed.

Hence, in yet another aspect of the present invention there is provided apparatus for use in a method of arthroplasty on a knee joint of a patient, comprising;

(a) a set of spacers for allowing selection of at least one said spacer for insertion into the knee joint for providing a desired spacing of the femur from the tibia; and

(b) at least one guide jig for guiding cutting of one or both of the tibia and the femur for resection of bone to a desired depth from the or each one respectively, to enable fitting of chosen tibial and femoral prostheses;

wherein the guide jig is adapted for being secured about the knee joint in a position determined by the spacer to guide the cutting of the one or both of tibia and the femur substantially at the desired said depth in the or each one, and wherein the spacers

have a different thickness to one another for providing different spacings of the femur from the tibia.

The guide jig may be adapted for guiding the cutting of the femur and the tibia at the same depth in each one or at a different depth in the tibia compared to the femur.

Preferably, the guide jig will be adapted for guiding the cutting of the tibia and the femur at a predetermined fixed spacing. The guide jig will normally be adapted for being coupled with one or more said spacers. The term "coupled" is to be taken in the broadest sense and includes within its scope reception of the spacer(s) by the jig whether the or each spacer is fixed to the guide jig or not.

Preferably, the guide jig will comprise a cutting block adapted for receiving the or each selected spacer and most preferably, will have a through passageway for guiding the cutting of one of the condyles of tibia and the femur. More preferably, the guide jig will have another through passageway for guiding the cutting of the other of the condyles. Most preferably, the cutting block will be adapted for being secured to the tibia.

Generally, the guide jig will be adapted for guiding cutting of one or both of the tibia and the femur in a medial to lateral or lateral to medial direction with respect to the knee joint.

Preferably, the guide jig will be adapted for being secured about the knee joint in a position determined by the thickness of the spacer or spacers used.

In another aspect of the present invention there is provided a spacer for being inserted into a knee joint for spacing the femur from the tibia, comprising an elongate member with a leading end region adapted for being positioned between the tibia and the femur to space the femur from the tibia, and an opposite end region for protruding from the knee joint.

In a further aspect of the present invention there is provided a spacer for being inserted into a knee joint to provide a desired spacing of the femur from the tibia in arthroplasty on the knee joint, comprising an elongate member with a leading end region adapted for being inserted between the tibia and the femur to thereby obtain the desired spacing of the femur from the tibia and being retained in the knee joint during resection of bone to a desired depth from one or both of the tibia and the femur respectively, and an opposite end region adapted for protruding from the knee joint and coupling with a guide jig for guiding the cutting of the or each one of the tibia and the femur in the resection of the bone.

Preferably, the leading end region of the spacer will be adapted for retaining the spacer in the knee joint. Most preferably, the leading end region of the spacer will be adapted for receiving the medial or lateral condyle of the femur for retaining the spacer in the knee joint.

In yet another aspect of the present invention there is provided a set of spacers for allowing selection of at least one of the spacers for insertion into a knee joint to provide a desired spacing of the femur from the tibia in arthroplasty on the knee joint, each said spacer respectively comprising an elongate member with a leading end region adapted for being inserted between the tibia and the femur to thereby space the femur from the tibia and being retained in the knee joint during resection of bone from one or both of the tibia and the femur respectively, and an opposite end region adapted for protruding from the knee joint and coupling with a guide jig for guiding cutting of the or each one of the tibia and the femur in the resection of the bone, wherein the spacers have a different thickness to one another for providing different spacings of the femur from the tibia.

3DOCID: <WO___0166021A1_I_>

Usually, it is desirably to resect the tibia at an angle sloping downwardly in the anterior to posterior direction of the knee joint for location of the tibial prosthesis on the resulting sloping surface of the tibia. Typically, the angle of slope is about 3° although this may vary from patient to patient.

Accordingly, in another aspect of the present invention there is provided an alignment device for aligning a guide jig in position about a knee joint for guiding cutting of at least one of the tibia and the femur at a desired location on the or each one respectively during arthroplasty on the knee joint, and comprising:

a body for receiving the guide jig and coupling the guide jig with an alignment guide for aligning the guide jig in a desired medial to lateral orientation with respect to the knee joint;

and wherein the body is adapted for aligning the guide jig at a desired angle in an anterior to posterior direction of the knee joint for securing of the guide jig at the desired angle prior to removal of the body from about the knee joint for allowing cutting of the one or both of tibia and the femur to be guided by the guide jig.

In still another aspect of the present invention there is provided an alignment device for supporting a cutting device for resecting bone from the tibia to a desired depth to from a recess in the tibia during arthroplasty on a knee joint, and comprising:

a body for receiving a guide jig for guiding cutting of the femur and coupling the guide jig with an alignment guide for aligning the guide jig in a desired medial to lateral orientation with respect to the knee joint;

and wherein the body is adapted for aligning the guide jig at a desired angle in an anterior to posterior direction of the knee joint and for being secured about the knee joint

in a position determined by the guide jig for supporting the cutting device for the resection of the bone from the tibia following removal of the guide jig from the body.

Accordingly, there is also provided an alignment guide for supporting the guide jig and aligning the guide jig in a desired medial to lateral orientation with respect to the knee joint to allow for varus and valgus adjustment.

The alignment guide will typically incorporate a mounting platform which is angularly displaceable for allowing orientation of the guide jig in the medial to lateral direction. Desirably, the mounting platform will be adapted for supporting the guide jig adjacent to the medial condyles of the tibia and femur or the lateral condyles of the bones as may be required. The alignment guide will generally be a tibial alignment guide for being secured along the leg of the patient in alignment with the tibia.

Alternatively, the guide jig itself may be adapted for guiding the cutting of one or both of the tibia and the femur at the desired angle in the medial to lateral direction of the knee joint. Similarly, the guide jig may be adapted for guiding cutting of the one or both of the tibia and femur at the downward angle in the anterior to posterior direction of the knee joint, in which case the alignment component described above for this purpose may not be utilised and the cutting block may be mounted directly on the alignment guide.

In still another aspect there is provided the use of a guide jig of the invention in the assembly of a medical device for arthroplasty of the knee, wherein the medical device comprises the guide jig and at least one spacer for spacing the femur from the tibia.

In still another aspect there is provided the use of at least one spacer of the invention in the assembly of a medical device for guiding resection of bone from at least one of the tibia and the femur in arthroplasty of the knee.

DOCID: <WO 0166021A1 I >

In a further aspect there is provided the use of at least one spacer of the invention in the assembly of a medical device for knee arthroplasty, wherein the medical device comprises the or each spacer and a guide jig of the present invention.

Advantageously, the method of the invention may allow balancing of tension in ligaments and other soft tissue structures of the knee joint to be optimised prior to resection of bone for the fitting of the prostheses. Moreover, ligament and soft tissue release to obtain adequate balancing of tension in the ligaments and soft tissue of the knee joint during flexion and extension of the knee joint as is required for optimum knee joint kinematics prior to or following fitting of trial tibial and femoral implants may be eliminated or reduced.

In addition, the risk of incorrect alignment and orientation of the tibial and femoral prostheses relative to one another with reference to the action of the ligaments and soft tissue structures may be reduced.

It is another advantage that as the use of a spacer or spacers as herein described may facilitate both positioning of the guide jig and appropriate tensioning of ligaments and other soft tissue structures of the knee joint, decreased operating times may be provided thereby potentially reducing the incidence of various time related surgical complications such as wound infection, complications associated with the risk of anaesthetic, and thrombosis associated with tourniquet application which can lead to pulmonary embolus and other serious problems. Furthermore, by reducing the need to transect, elevate, or release ligaments and other soft tissue structures of the knee joint, post-operative recovery time may be reduced with consequential reductions in overall health care costs associated with knee arthroplasty.

Unless the context clearly requires otherwise, throughout the description and the claims, the words 'comprise', 'comprising', and the like are to be construed in an inclusive sense as opposed to an exclusive or exhaustive sense; that is to say, in the sense of "including, but not limited to".

The features and advantages of the present invention will become further apparent from the following detailed description of a number of preferred embodiments illustrated in the accompanying drawings.

Brief Description Of The Accompanying Drawings

Figure 1 is a side schematic view illustrating a knee joint with tibial and femoral prostheses fitted;

Figure 2 is an anterior view of the fitted tibial and femoral prostheses shown in fig. 1;

Figure 3 is a perspective view of the femoral prostheses shown in fig. 1 prior to being fitted;

Figure 4 is a perspective view of the tibial prostheses shown in fig. 1 prior to being fitted;

Figure 5 is a diagrammatic front view of a knee joint;

Figure 6 is a diagrammatic front view showing a spacer in position between a femur and a tibia of the knee joint illustrated in fig. 5;

Figure 7 is a diagrammatic side view of a set of different spacers, for providing different spacing of the femur from the tibia;

Figure 8 is a perspective exploded view of apparatus for performing arthroplasty on a knee joint;

Figure 9(a) is a perspective view of the apparatus of fig. 8 when assembled;

Figure 9(b) is a diagrammatic front view of the apparatus of fig. 8 fitted to the leg of a patient;

Figure 10(a) is a rear perspective view of a guide jig of the apparatus shown in fig. 8;

Figure 10(b) is a side view of the guide jig of fig. 10(a);

Figure 11 is a view of an alignment component of the apparatus shown in fig. 8.

Figure 12 is a schematic plan view of the guide jig of fig. 10 indicating the orientation of channels defined in the jig for reception of pins for securing the jig in position about the knee joint;

Figure 13 is a diagrammatic partial view of a tibial shaft;

Figure 14 is a diagrammatic front view of the guide jig fitted in position about the knee joint;

Figure 15 is a front diagrammatic view showing the medial condyles of the femur and the tibia following resection thereof;

Figure 16 is a diagrammatic view illustrating the use of a tibial sizing device for determination of an appropriate size of tibial implant;

Figure 17 is a perspective view of a tibial trial;

Figure 18 is a diagrammatic view of the tibial trial of fig. 17;

Figure 19 is a diagrammatic anterior view of the tibial implant of fig. 16 fixed in position on the tibia of the knee joint;

Figures 20 and 21 are diagrammatic views illustrating marking of a femoral condyle of the knee joint for further resection of the femur to enable fitting of the femoral prosthesis of fig. 3;

Figure 22 is a diagrammatic view illustrating the use of a femoral sizer for determination of the appropriate sized femoral prosthesis;

Figure 23 is a diagrammatic view illustrating the use of a femoral shaping rasp for shaving bone from the relevant condyle of the femur to enable fitting of the femoral prosthesis;

Figure 24 is a diagrammatic view illustrating the use of a femoral peg drill guide to drill a bore into the femur for reception of the femoral peg of the femoral prosthesis shown in fig. 3;

Figure 25 is a perspective view of a tibial implant of the invention;

Figure 26 is a diagrammatic view of the tibial implant of fig. 25 fixed in position on the tibia;

Figure 27(a) is an elevated side view of a cutting device for resecting bone from the femur;

Figure 27(b) is a perspective view of the cutter blade disk of the cutting device of fig. 27(a);

Figure 28 is an end view of the cutting device of fig. 27(a);

Figure 29 is a side view of the cutting device of fig. 27(a);

Figure 30(a) is a longitudinal cross-sectional view of the cutting device of fig. 27(a);

Figure 30(b) is a diagrammatic partial view of a coupling arrangement used for coupling the head and body of the cutter device of fig. 27(a) together;

Figures 31 and 32 illustrate reception of the cutting device of fig. 27(a) the tibial implant of fig. 25 in unicondylar arthroplasty;

Figures 33(a) to 33(c) illustrate the resection of bone to a desired depth from the femur;

Figure 34 is an exploded perspective view of an assembly for forming a recess in the tibia for receiving a tibial implant;

Figure 35 is an exploded perspective view of the apparatus of fig. 8 when arranged for removal of bone from the tibia for inset placement of a tibial implant;

Figure 36 is a perspective view of the apparatus arranged as shown in fig. 35 when assembled;

Figure 37 illustrates removal of bone from the tibia for inset tibial implant placement utilising apparatus of the invention; and

Figure 38 illustrates a further cutting device for resecting bone to a desired depth from the femur.

Detailed Description Of Preferred Embodiments Of The Present Invention

The femoral prosthesis 2 shown in fig. 1 is fitted to the medial condyle 4 of the femur 6 and abuts articulating surface 8 of the tibial prosthesis 10 fitted on the corresponding medial condyle 12 of the tibia 14, for articulation thereon as the tibia undergoes flexion and extension about the knee joint 15. The positioning of the femoral prosthesis 2 and the tibial prosthesis 10 is more clearly shown in fig. 2.

As shown in fig. 3, the femoral prosthesis 2 is provided with a centrally orientated upstanding fin 16 incorporating a peg 18 projecting from an interior face 20 of the prosthesis.

The opposite outer face 22 has a curved contour for facilitating movement of the tibia about the femur. The interior face 20 of the femoral prosthesis is textured to enhance binding of bonding cement used to fix the prosthesis to the femur. The

prosthesis itself is formed from a cast cobalt chromium molybdenum alloy conventionally used in the manufacture of such prostheses.

The tibial prosthesis 10 shown more clearly in fig. 4 is manufactured from ultra high molecular weight polyethylene and has a dove tailed base 24 to again enhance bonding of cement to the prosthesis for fixing the prosthesis to the tibia. The articulating surface 8 of the tibial prosthesis is sightly concaved to substantially match curvature of the outer face 22 of the femoral prosthesis.

An example of unicondylar arthroplasty will now be described. As a first step, a longitudinal incision is made in the knee from just medial to the medial edge of the patella 26 to just below the medial tibial plateau adjacent to the attachment of the iliotibial tract, as indicated by the dotted line in fig. 5. The incision avoids transecting any of the ligamentous structures that contribute to the kinematics of the knee. The patella is not everted, but gently retracted laterally to expose the medial compartment of the knee. All femoral and tibial osteophytes which are accessible are then removed.

In order to balance tension in ligaments and other soft tissue structures of the knee joint as well as to correct deformity, a spacer 28 is located in position between the condyle of the femur and the corresponding condyle of the tibia as shown in fig. 6. The spacer effectively spaces the femur from the tibia.

To check for adequate tension of the soft tissue structures and kinematics of the knee joint, the tibia is moved through an arc of flexion of between 0° to about 130°. If the knee joint is unstable or has inadequate tension, the spacer may be removed and a spacer having a greater thickness for spacing the tibia and the femur further apart may be located in the joint. Conversely, if the knee feels over tensioned or adequate range of movement through the arc of flexion cannot be achieved, the spacer may be replaced

3DOCID: <WO__0166021A1_I_>

with a spacer having a reduced thickness to decrease the spacing between the femur and the tibia. This process may be repeated a number of times using a spacer having a different thickness each time until adequate tension and kinematics of the knee joint is achieved.

Importantly, the method enables the tensioning of soft tissue structures in the knee joint to be optimised prior to any bone being resected from the tibia or the femur in preparation for fitting of the tibial and femoral prostheses. Moreover, the tensioning may be obtained without the need to transect, elevate or release soft tissue structures of the knee joint. However, further adjustment of the tensioning in the knee joint as may be deemed necessary using such procedures is not excluded.

A set of spacers from which the appropriate spacer 28 may be selected is illustrated in fig. 7. The spacers each comprise an elongate body 30 for being inserted into the knee joint between opposing condyles of the tibia and the femur. The body 30 has a bulbous protrusion 32 formed on an underside of a leading end region 34 thereof for being seated on the sulcus of the relevant tibial condyle. As can be seen, the leading end region of each spacer is scooped upwardly forward of transverse ridge 35 thereby defining a trough 36 for receiving the condyle of the femur. The scooped contour of the leading end region of the spacer facilitates insertion of the spacer into the knee joint and assists in retaining the spacer in position once located in the knee joint.

As will be appreciated, the spacing of the femur from the tibia is determined by the thickness of the bulbous protrusion. In the spacer set shown, the thickness of the respective spacers increases in 1 mm increments. However, sets of spacers having a different thickness range may of course be used instead.

Once the appropriate spacer 28 has been selected and located in position in the knee joint, apparatus as shown in fig. 8 for guiding cutting of the tibia and the femur for resection of bone therefrom is secured in position about the knee joint. The apparatus comprises a guide jig in the form of a tibiofemoral cutting block 38 adapted for being securely mounted on mounting platform 40 of tibial alignment guide 42.

Tibial alignment guide 42 is adapted for being aligned along the longitudinal axis of the tibia and the mounting platform 40 is able to be angularly adjusted relative thereto about pivot 44 to accommodate required varus or valgus adjustment in the medial to lateral direction of the knee joint as may be necessary. Angular displacement of the mounting platform is achieved by loosening lock nut 52 and rotating the platform about the pivot pin 44 to the desired angle with reference to a scale (not shown) marked on the front face 54 of the tibial alignment guide, and subsequently retightening the lock nut 52. Shaft 46 of the alignment guide is telescopic to permit an ankle strap 48 carried on the bracket 50 mounted on the lower end region of the alignment guide to be secured around the ankle.

A more detailed view of the cutting block 38 is shown in fig. 10(a). As indicated, a number of slots extending through the cutting block from a front face 56 to an opposite rear face indicated by the numeral 58 are defined in the cutting block. In particular, the cutting block incorporates an upper slot 60 for guiding cutting of the femur in the resection of bone therefrom, and a middle slot 62 for receiving the protruding end region of the spacer when inserted in the knee joint. A lower slot 64 is also defined in the cutting block for reception of rear tongue 66 of alignment component 68. The distance between the top 70 of the slot 62 and the bottom 72 of the lower slot 64 corresponds essentially to the thickness T of the tibial prosthesis 10 of fig. 4. A pair of inwardly

SDOCID: <WO___0166021A1_I_>

directed channels 73(a) and 73(b) are also defined in opposite side regions of the cutting block, one in each side region respectively, for guiding downwardly directed cuts into the tibia in the resection of bone therefrom. A side view of the cutting block 38 is shown in fig. 10(b).

The apparatus when assembled is shown in fig. 9(a) and when secured in position about the knee joint in fig. 9(b). As can be seen, the apparatus further incorporates a stylus 75 for assisting alignment of the cutting block with the femur and which is mounted on the protruding end of the spacer 28.

As shown in fig. 11, the alignment component consists of a body 74 incorporating a forwardly projecting tongue 76 which lies in the same plane as rearwardly projecting tongue 66 and overlies a long tongue 78 of the body provided for insertion into slot 80 or 82 of the mounting platform 40 of the tibial alignment guide 42. The plane in which the forward and rearward tongues 76 and 66 lie extends at an angle ϕ relative to the long tongue 78 such that tongue 76 diverges from the long tongue 78 with distance along the long tongue.

Accordingly, the cutting block 38 when mounted on the alignment component and assembled with the tibial alignment guide 42 is orientated for guiding resection of bone at a downward angle of ϕ in the anterior to posterior direction of the knee joint. Typically, angle ϕ will be 3° although different alignment components may be provided in which angle ϕ differs from one to the next to allow selection of the most appropriate one for each patient. Alternatively, an alignment component may be utilised in which the tongues 66 and 76 lie substantially parallel with the long tongue 78 in the case where it is desirable for the tibia to be cut in a substantially horizontal plane of the tibia.

As will be appreciated, the slots 80 and 82 of the mounting platform 40 of the tibial alignment guide are spaced apart from each other along the mounting platform for allowing the cutting block 38 to be positioned adjacent to the lateral and medial condyles of either the right or left tibiae, respectively.

Once the cutting block is secured to the tibia as will be described further below, the alignment component 68 and the tibial alignment guide 42 are removed from about the knee joint without disturbing the cutting block and spacer assembly. This leaves lower guide slot 72 of the cutting block vacant for reception of a saw and subsequently guiding cutting of the medial condyle of the tibia in the resection of bone for fitting of the tibial prosthesis. The resection of bone from the tibia and the femur is performed while the knee is placed in about 90° to about 100° of flexion.

In this position, the top slot 60 of the cutting block 38 guides the saw for cutting of a posterior chamfer from the femoral condyle for fitting of the femoral prosthesis and as such, both the tibia and the femur are cut in a plane extending in the medial to lateral direction, respectively.

Channels 84 and 86 are provided in the cutting block for reception of trocar pins 88 for securing the cutting block to the tibia. As shown schematically in fig. 12, the bottom channels 86 converge toward each other in the front to the rear direction of the cutting block and are obliquely orientated with respect to the top pair of channels 84. Apertures 90 defined in the alignment component 68 are positioned to align with channels 84 of the cutting block when the cutting block is mounted on the tibial alignment guide to thereby hold the cutting block and alignment component together upon trocar pins being inserted therethrough into the tibia. In this way, the alignment

component can be slid off the free end of the trocar pins leaving the cutting block behind in position about the knee joint.

In the case of bowed varus tibiae, the cutting block will be arranged substantially perpendicular with respect to the metaphyseal axis of the tibial shaft as indicated in fig. 13.

Fig. 14 illustrates the positioning of the cutting block 38 for the resection of the medial condyles of the tibia and femur while the tibia is placed in flexion with respect to the femur, and with the alignment component 68 and tibial alignment guide 42 removed. Once the transverse cuts to the tibia and the femur have been performed, a downwardly directed cut into the tibia guided by the relevant one of channel 73(a) or 73(b) of the cutting block is performed for removal of a segment of bone from the tibia to form a recess therein. The cutting block 38 and spacer 28 assembly is then removed to allow the downwardly directed cut into the tibia to be completed. At this time, any remaining posterior osteophytes and meniscus are also removed as required. The resected medial condyles of the tibia and femur following removal of the cutting block and spacer assembly is shown in fig. 15. The use of a knee joint spreader 92 to maintain suitable access to the knee joint space is also shown. Alternatively, a suitable retractor may be utilised.

A diagrammatic plan view of the resected tibia is shown in fig. 16 . As indicated, following resection of the tibia, a tibial sizing device 94 is used to check the anteroposterior dimension of the resected tibial surface 96 for selection of an appropriately sized tibial trial 98 for being pinned into position on the resected surface. An example of a suitable tibial trial is illustrated in fig. 17.

The profile of the tibial trial 98 and its thickness T match that of the tibial prosthesis 10. As will be appreciated, and with reference to fig. 16, the profile of both the tibial trial 98 and tibial prosthesis 10 substantially match the profile of the resected tibial surface 96 of the tibia.

A channel in the form of a guide groove 100 is defined across the tibial trial for being orientated in the anteroposterior direction when the tibial trial is fitted in position. An obliquely orientated channel 102 extends from the side face 104 of the tibial trial through to its base 106 for reception of a pin therein for securing the tibial trial to the tibia. A tab 108 on the posterior side of the tibial trial depends from the base 106 as is more clearly shown in the diagrammatic size view of the tibial trial shown in fig. 18, for assisting positioning of the tibial trial on the resected surface of the tibia.

The tibial trial when secured in position on the resected tibial surface 96 of the tibia by pin 110 is shown in fig. 19. To accommodate the upstanding central fin 16 of the femoral prosthesis 2, a reciprocating saw blade is located along the guide groove 100 of the tibial trial and the tibia moved about the femur through an arc of motion to cut a channel into the femur indicated by dotted line 112. In this way, the groove 100 of the tibial trial determines the correct orientation for fitting of the femoral prosthesis on the femur.

As an alternative, rather than cutting the channel into the femur as described above, a marker pen or diathermy can be used in place of the saw blade for marking of the femoral condyle for subsequent cutting of the channel into the femur using a saw blade in a free hand manner.

With the knee in full extension, and with care being taken not to hyperextend the knee, an imaginary line aligned with the groove 100 of the tibial trial is projected from

the anterior side of the tibial trial 98 to the corresponding femoral medial condyle as indicated in fig. 20. The point 114 at which the line strikes the femur is marked and corresponds to the optimal position of the anterior edge 116 of the femoral prosthesis 2, and is indicated more clearly in fig. 21 where the tibia is shown in flexion relative to the femur.

A femoral sizer 118 is then aligned with the channel cut into the femur, with the posterior end 120 of the femoral sizer positioned flushly against the resected posterior face 122 of the femoral condyle, to allow determination of the required size of femoral prosthesis 2 by comparing the position of the mark 114 with calibrated markings on the femoral sizer as shown in fig. 22.

The femoral condyle can then be sculpted as required to accommodate the fitting of the femoral prosthesis 2. This can be readily achieved with the use of a cutter device such as a femoral shaping rasp 124 illustrated in fig. 23 or for instance, a router having a rotatable cutter for resecting bone from the femur. As can be seen, the rasp 124 has a tang 126 for being received by a reciprocating power saw. The body 128 of the rasp is generally flat and is provided with a tapered leading end 130. A key (not shown) extends centrally along the base of the rasp for reception in the guide groove 100 of the tibial trial 98. Accordingly, the groove of the tibial trial 98 acts to guide the reciprocating motion of the rasp when positioned on the tibial trial under the femur as illustrated in fig. 23.

As will be understood, to sculpt the femur, the tibia is rotated about the femur through an arc of motion between forward and backward positions during which movement the cutting face of the rasp acts to progressively shave away the required thickness of the femur. It will also be appreciated that the thickness of the rasp is such to ensure that the original spacing between the femur and the tibia provided by the selected

spacer 28 will be essentially retained upon the femoral prosthesis being fitted, for substantially maintaining the optimised balance in ligaments and other soft tissue initially provided by the spacing of the femur from the tibia by the selected spacer.

Drilling of the required bore 132 into the femur for reception of the peg 18 of the femoral prosthesis is readily achieved using a femoral peg drill guide 134 carrying a guide bracket 136 having a corresponding shape to the femoral prosthesis. Determination of the position for drilling the bore 132 is achieved by aligning the anterior tip 138 of the guide bracket 136 over the location 114 determined on the femur to correspond with the optimal positioning of the anterior end of the femoral prosthesis and reference is drawn to fig. 24 for explanatory purposes.

Subsequently, the joint space is lavaged and a femoral trial affixed to the femur for a final assessment of joint stability and joint kinematics.

The tibial and femoral trials are then removed and the joint space thoroughly cleaned using pulsatile lavage prior to the tibial prosthesis 10 and the femoral prosthesis 2 being fixed to the tibia and the femur respectively, using appropriate conventionally known bonding cement such as polymethylacrylate bone cement. Prior to closing the wound the joint space is again thoroughly lavaged and if deemed necessary, local anaesthetic may be infiltrated at the wound site to assist post operative pain relief.

As will be appreciated, the tibial prosthesis used in a method as described herein may be selected from a number of such prostheses with a different thickness T to each other. The selected prosthesis will of course depend on the thickness of the spacer 28 required to initially optimise tension and balance in the action of the relevant ligaments and soft tissue structures of the knee joint during the movement of the tibia about the femur between forward and backward positions. For each thickness of tibial prosthesis,

DOCID: <WO 0166021A1 >

a corresponding cutting block 38 for guiding cutting of the tibia and the femur at the required spacing to accommodate the selected tibial prosthesis will be provided. Alternatively, a cutting block able to be adjusted to alter the spacing between the guide slots 60 and 62 as necessary to correspond to the thickness T of the selected tibial prosthesis may be used.

Another embodiment of a tibial trial 98 having a guide channel 140(a) extending part way across the tibial trial in a generally anteroposterior direction is shown in fig. 25 for reception of a router. The channel 140(a) has a dove tailed cross-section lying in a plane extending perpendicularly with respect to the major axis of the tibial trial. An identical channel 140(b) is defined in the underside of the tibial trial. As can be seen, this tibial trial is again provided with a channel 142 which extends from the upperside face 140 of the tibial trial through to its base 146 for reception of an obliquely orientated trocar pin therein for securing the tibial trial to the tibia. A further channel 148 is defined on the opposite side of the tibial trial for reception of an obliquely directed trocar pin. Indeed, the tibial trial is designed such that the tibial trial may be secured to either the medial condyle or the lateral condyle following the resection of bone therefrom. That is, by simply rotating the tibial trial 180° about its major axis the trial can be pinned to either medial lateral resected surfaces 96 of the tibia by the insertion of trocar pins through channels 142 and 148. The tibial trial when secured in position on the tibia prior to receiving the router is shown in fig. 26.

The router 150 shown in fig. 27(a) comprises a flat head 152 having a substantially constant thickness along its length and which is detachably connected to body 154 of the router. A cutter disk 156 is seated in an aperture defined in the upperside 158 of the router head 152. A forward guard 160 is defined on the leading end 162 of the router.

An end view of the router is shown in fig. 28 and a side view in fig. 29. As can be seen, a boss 164 having a dove tailed profile corresponding to that of the guide channel 140(a) of the tibial trial of fig. 25 depends from the underside of the router 150 for reception in the guide channel 140(a) for thereby inhibiting lifting of the router from the tibial trial.

The cutter disk 156 is more clearly shown in fig. 27(b) and has a dished upper surface 165 and a plurality of radially directed blades 166. Each blade decreases in thickness from a leading cutting edge 168 to a trailing edge 170. A further cutting edge 172 is defined at the outer peripheral end of each blade. In addition, an integrally formed upstanding cutting blade 174 is centrally located on the cutter disk. The upstanding blade 174 has a plurality of upwardly directed cutting edges 176 spaced at 120° intervals around the blade. Specifically, the cutting edges 176 are defined on both the side and top end of the upstanding blade as can be seen.

Turning now to fig. 30(a), the cutter disk 156 further incorporates an integrally formed drive gear 178 with a plurality of vertically orientated teeth 180 which mesh with the screw of the screw drive 182 rotatably received within the head 152 of the router 150.

The cutter disk 156 has an internal female thread which mates with a screw 186 extending through collet 188 received in recess 190 defined in the underside of the router head, such that the cutter disk 156 is thereby retained in position on the router head and is rotatable with respect to the router head.

A drive shaft 192 is rotatably mounted within the router body and projects therefrom for engagement with the female bayonet coupling 194 of the screw drive 184 of the router head. As shown in fig. 30(b), the projecting end 196 of the drive shaft 192 carries bayonet pin 198 for reception in the bayonet recesses 200 of the bayonet coupling

for thereby locking the router head 152 to the router body 154. The projecting end 196 of the drive shaft 192 is further provided with a flat drive projection 202 which slots into the slot 204 of the bayonet coupling for driving rotation of the screw drive 184 and so causing rotation of the cutter disk 156. The router body is adapted for being coupled with a power drive for driving rotation of the cutter disk typically in the range of from 5,000 rpm to about 7,000 rpm. As will be understood, once used, the router head 152 may be removed and discarded. Desirably, however, the body 154 of the router is sealed and is reusable following sterilisation.

Rather than engaging the cutter disk directly, the screw drive 184 of other embodiments may be arranged to drive a gear arrangement comprising a single gear or for instance a gear train incorporating a number of gears for driving the cutter disk. Alternatively, the router may incorporate a drive in the form of an endless belt, band or the like which upon being driven by the drive shaft causes rotation of the cutter disk.

As indicated above, the cutter disk 156 is freely rotatable with respect to the head of the router and may be lifted from the head upon the screw 186 being removed to allow replacement of the cutter disk with another of the same or different design. A blunt cutter disk may result in thermal necrosis of bone of the femur and accordingly it is desirable to replace the cutter disk if necessary. To assist in the insertion of the router into the knee joint, the leading end 162 of the head of the router has an arcuate profile.

The insertion of the router into the knee joint is indicated in figs. 31 and 32, and the use of the tibial trial of fig. 26 and router 150 in unicondylar knee arthroplasty is illustrated in figs. 33(a) to 33(c). Specifically, the tibia is again placed in flexion with respect to the femur, and the boss 164 of the router is inserted into the guide channel 140(a) of the tibial trial as shown in fig. 32. Upon operation of the router and the tibia

being moved about the femur through an arc of motion to an extended position, bone is resected from the femur to the desired depth in the direction of movement of the tibia as shown in fig. 33(b). As indicated more clearly in fig. 33(c), the channel 206 for reception of the central fin 16 of the femoral prostheses is simultaneously cut into the femoral condyle by upstanding blade 174 of the cutter disk 156 of the router 150.

Rather than cutting the channel 206 for reception of the central fin of the femoral prosthesis simultaneously with the resurfacing of the femur utilising the cutter disk 156, the resurfacing of the femur and the cutting of the channel 206 may be achieved in a two stage process. That is, a cutter blade may be located in the router for cutting the channel in an initial step, and then that cutter blade replaced with one for resecting the required thickness of bone from the femur and which incorporates an upstanding centrally located non-cutting boss for reception in the cut channel 206 to thereby guide the resurfacing of the femur. In this instance, the boss will generally be of a height such that a space remains between the upper end of the boss and the overlying roof of the channel.

Similarly, rather than resecting the posterior chamfer from the femur with a reciprocating saw utilising the cutting block 38 for guidance, the posterior chamfer may be resected from the femur with the use of a router 150 in which the router head 152 is provided without a guard 160. As such, a cutting block may be provided that while being capable of being coupled with the spacer selected for optimum spacing of the femur from the tibia as described above, may only be adapted for guiding cutting of the tibia at the relevant depth therein and not the femur.

While the method has been described in relation to arthroplasty performed on the medial condyles of the tibia and the femur, unicondylar arthroplasty may be performed on the lateral condyles in the same manner.

In addition, rather than removing the entire upper segment of the relevant condyle of the tibia in unicondylar arthroplasty to provide an exposed recess on which the tibial trial and subsequently the final tibial prosthesis 10 is onset and fixed in position as described above, a recess may be formed in the condyle into which the tibial trial and ultimately the tibial prosthesis are inset, respectively. An apparatus for providing such a recess in the tibia is shown in fig. 34.

The apparatus comprises a router 208 and a guide jig 210 for guiding the router to form the inset recess 212, in this case in the medial condyle of the tibia 14.

The router 208 has an elongated body 214 housing a drive shaft 216 for driving rotation of a router blade 218 in the same manner as described for the router shown in fig. 30, for resecting the bone from the tibia to the desired depth in the tibia. The drive shaft 216 projects from the trailing end 222 of the body 214 for reception by a power tool for driving rotation of the drive shaft.

A guide pin 224 projects from an underside of the router body 214 for reception in a recessed template 226 defined in the floor of channel 228 of the guide jig 210. A recessed area is also defined in the body of the router to allow the router to overlie the rim 232 of the recess and to allow the router blade to resect the bone from the tibia to the desired depth. The guide pin has a length to ensure reception in the recessed template of the guide jig when the router is positioned over the tibia prior to commencement of the resection of bone in the formation of the recess. Similarly, the depth of the recessed template is sufficient to ensure the entire exposed length of the guide pin is able to be accommodated therein.

The profile of the template 226 substantially matches the external profile of the tibial trial to be used, and the template is dimensioned for the recess to be of a size

sufficient to allow the tibial trial to be seated on the resected tibial surface 96 at the base of the recess. Once received in the recess, the surrounding bone of the tibia acts to inhibit the tibial trial and subsequently the actual tibial prosthesis 10 from being transversely dislocated.

In order to position the guide jig 210 about the knee, the tibiofemoral cutting block 38 is firstly arranged adjacent to the tibia in the manner described above utilising the selected spacer 28 to determine the position of the cutting block with respect to the tibia, prior to the securing of the cutting block in position using trocar pins 234. As will be understood, trocar pins 234 are dimensioned for being inserted into the channels 84 and 90 of the cutting block and alignment component in a sliding fit and to allow the cutting block and alignment component 68 to be slid from the pins following resection of the one or both of the tibia and femur as described above.

Once the cutting block and spacer assembly has subsequently been slid from the trocar pins the guide jig 210 is slid onto the trocar pins 234 such that the trocar pins are received in longitudinally extending parallel channels 236 of the guide jig.

The router blade 218 projects from the head 220 of the router a distance such that when the router is received in the channel 228 of the guide jig, bone is able to be resected from the tibia to a depth corresponding to the position of the bottom 72 of the lower slot 64 of the cutting block 38 prior to removal of the cutting block from the tibia. Resection of bone from the tibia beyond this depth is inhibited by abutment of the underside surface 238 of the rear end region 240 of the router with the floor 242 of the channel of the guide jig. To resect bone from the tibia to greater depths to accommodate different sized tibial trials, different sized router blades may be utilised on the router.

In order to enhance stability, the guide jig is provided with a rest 244 that projects downwardly from the leading end 246 of the guide jig and which rests against the leg of the patient to thereby assist in maintaining the jig in position at the angle in the anterior to posterior direction determined by the alignment component 68. The guide jig is secured in position on the tibia by pin 248 inserted into the tibia through channel 250 defined in the rest 244 which channel extends at an oblique angle with respect to parallel channels 236 of the guide jig receiving trocar pins 234.

The recess 212 in the tibia is formed and shaped by the application of downward pressure to the router as the router is moved side to side and forward and backward in the guide jig, the movement of the router across the tibia being limited by the restricted field of movement of the guide pin in the recessed template of the jig. Accessible tibial osteophytes may be removed prior to or following the formation of the recess in the tibia. To allow for the resection of differently sized recesses, a range of guide jigs may be provided with templates of different width and length dimensions. Similarly, the location of the guide pin 224 on the router may be adjustable along the router to accommodate resection of the recess in the desired position on the tibia, or otherwise the guide jig may be adapted for facilitating adjustment of the position of the guide jig along the trocar pins. This may be achieved for instance by the rest being extendible relative to the remainder of the guide jig for causing the desired displacement of the template away from the knee joint.

The tibia trial when seated in the recess will typically protrude above the rim 232 of the recess. Usually, the tibial trial will be secured in position in the recess by an appropriately located pin inserted into the tibia at an oblique angle (not shown).

The channel for receiving the central fin 16 of the femoral prosthesis may then be cut into the corresponding condyle of the femur if not already achieved simultaneously during the resection of the femur with the use of a router of the type shown in fig. 30.

Rather than utilising a guide jig arrangement of the type shown in fig. 34 for resecting a channel into the tibia for insertion of a tibial trial and subsequently a tibial prosthesis therein, apparatus as shown in fig. 8 may more desirably be utilised. In this instance, rather than the cutting block 38 being mounted on the rearward tongue 66 of the alignment component 68, the cutting block is rotated 180° and mounted on the forward tongue 76 of the alignment component as indicated in the exploded view shown in fig. 35 and the view of the assembled arrangement indicated in fig. 36. Accordingly, in this instance the alignment component 68 is located between the cutting block 38 and the tibia 14 for resection of the posterior chamfer from the femur 6 as indicated above. Once the posterior chamfer has been resected, the cutting block 38 is slid from the alignment component 68 leaving the alignment component 68 behind in position relative to the tibia.

The body 74 of the alignment component is dimensioned such that the upper surface 252 of the head 254 is aligned at the same level as the bottom of the middle slot 62 of the cutting block for the spacer, prior to the cutting block being slid from the trocar pins securing the alignment component in position relative to the tibia. The upper surface 252, therefore, may therefore be used as a rest for a router 256 as shown in fig. 37 for removing bone from the tibia to form a recess to the desired depth for the seating therein of a tibial trial and thereafter the ultimate tibial prosthesis. That is, the height of the cutter blade 258 of the router 256 is dimensioned such that the floor of the recess resected into the tibia is at a level corresponding to the level of the bottom 72 of the

JSDOCID: <WO 0166021A1 I >

lower slot 64 of the cutting block when located in position adjacent to the tibia. As with the cutter blade of the router shown in fig. 30, the cutter blade 258 has cutting edges defined on both the sides and top end of the blade.

The correct size of the recess to be resected is firstly ascertained by locating different tibial trial templates on the tibial condyle and selecting the most appropriate one prior to marking the profile of the selected templated on the tibial trial in the required location with methylene blue or other suitable dye as is conventionally known in the art.

Following removal of the alignment component 68 for insetting of the tibial trial in the resected recess, the femur may be further resected as described above for the fitting of the femoral prosthesis.

Another router employing a cutter disk 260 is shown in fig. 38. This embodiment rather than being adapted for reception by a tibial trial, has a body 262 with a head 264 adapted for being seated on the base of the recess 212 resected into the tibia and which is dimensioned such that movement of the router when in position in the recess in a generally medial to lateral direction or vice versa is limited. The cutter disk is the same as that utilised on the router shown in fig. 30 and is arranged for resection of the femur to the desired depth in that bone in the manner described above upon movement of the tibia through an arc of motion about the femur.

In a bicondylar knee arthroplasty method, two small stab incisions are made in the knee with a scalpel blade to provide portals for insertion of a spacer in each one, respectively. The incisions are located medial and lateral to the patellar tendon to allow access to between the tibia and the femur, and are positioned so as to generally not coincide with ligamentous and other soft tissue structures of the knee.

A spacer is then introduced between the opposing lateral condyles and the opposing medial condyles of the tibia and the femur, respectively. The desired thickness of spacers required to obtain balance in the action of relevant ones of the ligaments and other soft tissue structures of the knee during flexion and extension of the tibia relative to the femur to provide appropriate tension in the knee joint and correction of varus or valgus deformity is determined substantially as described above using different thicknessed spacers.

Specifically, the tibia is moved about the femur between forward and backward positions and the kinematics of the knee evaluated. If necessary, one or both of the spacers may be substituted with one(s) of a different thickness and movement of the knee joint while the spacers are in position checked again. This may be repeated a number of times until the optimum spacing of the femur from the tibia is obtained. Accordingly, the spacers selected for optimum spacing of the femur from the tibia may have the same thickness as each other or a different thickness to each other depending on the degree of spacing required between the respective condyle pairs.

The spacers will usually be linked together by a cross-bar during the rotation of the tibia about the femur. The cross-bar may comprise a stiff metal member secured to each spacer by a clamp or suitable fastener respectively, or other such arrangement for inhibiting independent movement of the spacers.

In this way, the desired balancing and deformity correction of the knee joint may be achieved prior to surgically opening the medial and lateral compartments of the knee joint for resection of the medial and lateral condyles of the femur and the tibia.

Once the spacers for providing the optimum spacing of the femur and the tibia have been selected, unicondylar arthroplasty is performed on each of the medial and

lateral condyle pairs as described above, one pair at a time. Preferably, the condyle pair deemed to require the greater degree of deformity correction is subjected to arthroplasty first.

More particularly, bone may be resected from the tibia utilising either the tibiofemoral cutting block 38 or guide jig 210 to guide the resection of the bone. Once both the tibial and femoral trials have been fitted, arthroplasty is then performed on the other of the condyle pairs.

Prior to doing so, the spacer selected for spacing of those condyles apart is reinserted between them and the kinematics of the knee joint checked by rotating the tibia about the femur to confirm satisfactory kinematics of the knee joint. Bone is then resected from the tibial and femoral condyles of that pair to the desired depth in each one again utilising the spacer as reference for the positioning of the tibiofemoral cutting block 38 or guide jig 210. Upon fitting of the further tibial and femoral trials, the kinematics of the knee joint are checked once again to ensure adequate range of motion and retention of optimum tension in ligaments and other soft tissue structures of the knee joint. The respective tibial trials and femoral trials are subsequently removed and replaced with the final tibial and femoral prostheses. Generally, the tibial and femoral prostheses will be fitted to one condyle pair at a time.

Accordingly, the bicondylar knee arthroplasty method described comprises performing unicondylar knee arthroplasty as described herein on both medial and lateral condyle pairs of the knee. As will be further appreciated, the bicondylar arthroplasty method involves gently retracting the patella transversely about the knee joint to gain access to the medial or lateral compartment of the knee joint and, subsequently retracting the patella transversely about the knee joint in the opposite direction to gain access to the

other of the knee compartments. The method may also allow the quadricep system to remain substantially intact.

Moreover, as with the unicondylar arthroplasty technique described, the bicondylar knee arthroplasty method may allow the desired tensioning and deformity correction to be achieved substantially without the need to transect, elevate or release soft tissue structures of the knee joint although again, adjustment prior to or following fitting of the tibial and femoral trials is not excluded.

Accordingly, although the present invention has been described hereinbefore with reference to preferred embodiments, the skilled addressee will understand that numerous variations and modifications are possible without departing from the scope of the invention.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:-

1. A method of arthroplasty on a knee joint, comprising the steps of:

(a) obtaining a desired spacing of the femur from the tibia;

(b) determining depth of bone to be resected from at least one of the tibia and the femur on the basis of the desired spacing of the femur from the tibia to enable fitting of at least one prosthesis selected from tibial and femoral prostheses;

(c) resecting bone from one or both of the tibia and the femur substantially to the determined depth in the or each one, respectively; and

(d) fitting the or each said prosthesis.

2. A method according to claim 1 further comprising:

selecting at least one spacer for providing the desired spacing of the femur from the tibia; and

positioning the spacer in the knee joint between the tibia and the femur to thereby obtain the desired spacing of the femur from the tibia.

3. A method according to claim 2 wherein the selecting comprises:

(i) choosing the spacer from a range of spacers for providing different spacings of the femur from the tibia, respectively;

(ii) moving the tibia about the femur through an arc of motion between backward and forward positions to evaluate movement of the knee joint while the chosen said spacer is in position between the femur and the tibia.

4. A method according to claim 3 wherein the selecting further comprises repeating steps (i) and (ii) as necessary to obtain the desired spacing of the femur from the tibia using a different spacer chosen from the range of spacers each time.

5. A method according to any one of claims 2 to 4 further comprising placing the knee joint in a position of flexion whereby the tibia is arranged at an angle with respect to the femur for the resection of the bone.

6. A method according to any one of claims 2 to 5 further comprising :

locating a guide jig in position about the knee joint for guiding the resection of the bone; and

using the guide jig to guide cutting of the tibia substantially at the desired depth in a medial to lateral or lateral to medial direction in the resection of bone from the tibia.

7. A method according to claim 6 wherein the locating of the guide jig comprises utilising the spacer as a reference to determine the position of the guide jig about the knee joint for guiding the cutting of the tibia substantially at the desired depth.

8. A method according to claim 6 or 7 wherein the locating of the guide jig comprises coupling the guide jig with the spacer while the spacer is positioned in the knee joint between the femur and the tibia to thereby determine the position of the guide jig about the knee joint.

9. A method according to any one of claims 6 to 8 further comprising using the guide jig to guide cutting of the femur substantially at the desired depth to remove a chamfer from the posterior of the femur in the resection of the bone.

10. A method according to any one of claims 6 to 9 further comprising:

location a cutter device in position in the knee joint between the tibia and the femur; and

moving the tibia through an arc of motion about the femur between backward and forward positions while the cutting device is being operated and located between the

tibia and the femur, to thereby substantially remove bone substantially to the desired depth from the femur in a direction of travel of the tibia relative to the femur.

11. A method according to claim 10 further comprising:

removing the guide jig from said position about the knee joint; and

inserting a tibial implant in position in a recess in the tibia formed by the resection of the bone from the tibia;

wherein the tibial implant is adapted for reception of the cutter device thereon and maintaining the cutter device in a desired orientation with respect to the femur as the tibia is moved through the arc of motion between the backward and forward positions.

12. A method according to claim 11 wherein the tibial implant is a tibial trial and the method further comprises placing the cutter device on the tibial trial such that the tibial trial and the cutter device are coupled together prior to moving the tibia through the arc of motion.

13. A method according to any one of claims 1 to 12 further comprising:

cutting a channel into the femur for reception of an upstanding fin of a selected said femoral prosthesis, wherein the channel when formed lies in an anterior to posterior direction.

14. A method according to any one of claims 10 to 12 further comprising:

cutting a channel into the femur utilising the cutter device for reception of an upstanding fin of a selected said femoral prosthesis;

wherein the channel is cut into the femur simultaneously with the resection of the bone from the femur to the desired depth as the tibia is moved through the arc of motion about the femur.

15. A method according to any one of claims 1 to 14 wherein the bone is resected from a lateral or medial condyle of the tibia and a corresponding condyle of the femur.

16. A method according to claim 15 further comprising resecting bone from the other condyle of the tibia and the condyle of the femur corresponding to the other tibial condyle.

17. A method according to any one of claim 1 to 8 wherein the bone is resected from a lateral or medial condyle of the tibia only.

18. A method of arthroplasty on a knee joint, comprising the steps of:

(a) surgically providing access to the knee joint;

(b) selecting at least one spacer for providing a desired spacing of the femur from the tibia;

(c) positioning the selected spacer in the knee joint to obtain the desired spacing of the femur from the tibia;

(d) using the spacer as a reference to determine a location on each one of the tibia and the femur indicating depth of bone to be resected from each for fitting of chosen tibial and femoral prostheses;

(e) cutting the tibia and the femur substantially at the determined location on each for resection of the bone from each one to the required said depth from each one, respectively; and

(f) fitting the chosen tibial and femoral prostheses.

19. A method according to claim 18 wherein the selecting of the spacer comprises:

(i) choosing the spacer from a range of spacers for providing different spacing of the femur from the tibia, respectively; and

(ii) moving the tibia about the femur through an arc of motion between backward and forward positions to evaluate movement of the knee joint while the chosen said spacer is in position between the femur and the tibia.

20. A method according to claim 19 wherein the selecting further comprises repeating steps (i) and (ii) as necessary to obtain the desired spacing of the femur from the tibia using a different spacer from the range of spacers each time.

21. A method according to any one of claims 18 to 20 further comprising placing the knee joint in a position of flexion whereby the tibia is arranged at an angle with respect to the femur for the resection of the bone.

22. A method according to any one of claims 18 to 21 wherein the cutting of the femur comprises resecting a chamfer from the posterior of the femur.

23. A method according to any one of claims 18 to 22 further comprising:

locating a cutting device in the knee joint between the femur and the tibia; and

moving the tibia through an arc of motion about the femur between backward and forward positions while the cutting device is being operated to thereby remove bone substantially to the desired depth from the femur in a direction of travel of the tibia relative to the femur.

24. A method according to any one of claims 18 to 23 further comprising:

cutting a channel into the femur for reception of an upstanding fin of the femoral prosthesis, wherein the channel when formed lies in an anterior to posterior direction.

25. A method according to claim 23 further comprising:

cutting a channel into the femur utilising the cutter device for reception of an upstanding fin of the femoral prosthesis, simultaneously with the resection of the bone from the femur as the femur is moved through the arc of motion about the femur.

26. A method according to any one of claims 18 to 25 wherein the bone is resected from a lateral or medial condyle of the tibia and a corresponding condyle of the femur.

27. A method of arthroplasty on a knee joint, comprising the steps of:

(a) locating a cutting device in position in a knee joint between the femur and the tibia; and

(b) moving the tibia through an arc of motion about the femur between backward and forward positions while the cutting device is being operated to thereby remove bone substantially to a desired depth from the femur in a direction of travel of the tibia relative to the femur, for enabling fitting of a femoral prosthesis to the femur.

28. A method according to claim 27 further comprising:

resecting bone from the tibia to a desired depth to provide a prepared surface for placement of a tibial implant;

fixing the tibial implant in position on the prepared surface of the tibia, and

placing the cutter device on the tibial implant prior to moving the tibia through the arc of motion about the femur.

29. A method according to claim 28 wherein the tibial implant is adapted for mating with the cutter device and the placing of the cutter device on the tibial implant comprises mating the tibial implant and the cutter device together such that the cutter device is maintained in a desired orientation with respect to the femur as the tibia is moved through the arc of motion between the backward and forward positions.

30. A method according to claim 28 or 29 wherein the resection of bone from the tibia comprises cutting the tibia substantially at the desired depth in a medial to lateral or lateral to medial direction to thereby provide the prepared surface for placement of the tibial implant.

3DOCID: <WO 0166021A1 I >

31. A method according to any one of claims 27 to 29 wherein the resection of the bone comprises forming a recess in the tibia in which the tibial implant is fixed in position on the prepared surface.

32. A method according to claim 27 further comprising forming a recess in the uppermost end of the tibia to a desired depth for reception of the cutting device for removing the bone to the desired depth from the femur.

33. A method according to any one of claims 27 to 32 further comprising cutting a channel into a femur utilising the cutting device for reception of an upstanding fin of the femoral prosthesis, wherein the channel is cut into the femur simultaneously with the resection of the bone from the femur as the tibia is moved through the arc of motion about the femur.

34. A method of determining the position of a guide jig about a knee joint for subsequently guiding cutting of one or both of the tibia and the femur at a desired depth in the or each one respectively, the method comprising:

(a) locating a selected spacer in the knee joint to obtain a desired spacing of the femur from the tibia; and

(b) arranging the guide jig and the spacer together to thereby determine the position of the guide jig about the knee joint for guiding the cutting of the or each one of the tibia and the femur.

35. A method according to claim 34 wherein the spacer is selected from a range of spacers and the selecting of the spacer comprises:

(i) choosing the spacer from a range of spacers for providing different spacings of the femur from the tibia, respectively;

(ii) moving the tibia about the femur through an arc of motion between backward and forward positions to evaluate movement of the knee joint while the selected spacer is in position between the femur and the tibia.

36. A method according to claim 35 wherein the selecting further comprises repeating steps (i) and (ii) as necessary to obtain the desired spacing of the femur from the tibia using a different spacer chosen from the range of spacer each time.

37. A method according to any one of claims 34 to 36 wherein the arranging of the guide jig with the spacer comprises coupling the guide jig and the spacer together.

38. A method according to claim 37 wherein the coupling of the guide jig with the spacer comprises sliding the guide jig onto a protruding end region of the spacer protruding from the knee joint.

39. A method according to any one of claims 34 to 38 further comprising:

coupling the guide jig with an alignment component for aligning the guide jig relative to the knee joint at a desired angle in a posterior to anterior direction of the knee joint; and

securing the guide jig in said position such that the guide jig is aligned at the desired angle.

40. A method according to claim 39 wherein the alignment component is capable of being withdrawn from the guide jig leaving the guide jig behind secured in said position about the knee joint.

41. A method according to claim 39 wherein the alignment component for aligning the guide jig at the desired angle is arranged between the knee joint and the guide jig when the guide jig is secured in said position at the desired angle.

42. A method according to any one of claims 34 to 41 further comprising:

arranging the guide jig in a desired medial to lateral orientation with respect to the knee joint.

43. A method according to claim 42 wherein the arranging of the guide jig in the desired medial to lateral orientation comprises utilising an alignment guide for aligning the guide jig with respect to the tibia.

44. A guide jig for use in a method of arthroplasty on a knee joint of a patient, wherein the guide jig is adapted for guiding cutting of at least one of the tibia and the femur in resection of bone therefrom for enabling fitting of one or both of a tibia and a femoral prosthesis, and wherein the guide jig is further adapted for being arranged with a selected spacer for spacing the femur from the tibia and for being secured about the knee joint in a position determined by the spacer to guide cutting of at least one of the tibia and the femur substantially at a desired depth in the or each one, respectively.

45. A guide jig according to claim 44 wherein the guide jig is adapted for receiving the spacer for thereby determining the position of the guide jig about the knee joint.

46. A guide jig according to claim 45 wherein the guide jig has a through passageway for reception of the spacer for thereby determining the position of the guide jig about the knee joint.

47. A guide according to any one of claims 44 to 46 wherein the guide jig is adapted for guiding cutting of the tibia when secured about the knee joint is said position.

48. A guide jig according to any one of claims 44 to 47 wherein the guide jig is adapted for guiding cutting of both the tibia and the femur.

49. A guide jig according to claim 47 wherein the guide jig is adapted for guiding the cutting of the tibia and the femur at a fixed predetermined spacing from one another, respectively.

50. A guide jig according to any one of claims 44 to 47 wherein the guide jig is adapted for guiding the cutting of at least one of the tibia and the femur substantially in a medial to lateral or lateral to medial direction when secured about the knee joint in said position.

51. A guide jig according to claim 50 wherein the guide jig is a cutting block with a through slot for guiding the cutting of the tibia.

52. A guide jig according to claim 51 wherein the guide jig has a further through slot for guiding the cutting of the femur.

53. A guide jig according to any one of claims 44 to 52 wherein the guide jig is further adapted for guiding cutting in a direction along the tibia for resection of a segment of bone from the tibia.

54. A guide jig according to claim 53 wherein the guide jig is provided with at least one channel for guiding the cutting along the tibia for the resection of the segment of bone and extending from front through to the rear of the guide jig.

55. A guide jig according to claim 54 wherein the guide jig is provided with a pair of spaced apart said channels, one channel being defined in each one of opposite side regions of the guide jig, respectively.

56. A guide jig according to claims 54 or 55 wherein the or each said channel slopes inwardly at a desired angle with distance from an upperside to an opposite underside of the jig.

57. A guide jig according to any one of claims 44 to 56 wherein the guide jig is adapted for guiding the cutting of the tibia to provide a tibial surface sloping downwardly in an anterior to posterior direction of the knee joint when secured in position about the knee joint.

58. An alignment device for aligning a guide jig in position about a knee joint for guiding cutting of at least one of the tibia and the femur at a desired location on the or each one respectively during arthroplasty on the knee joint, and comprising:

a body for receiving the guide jig and coupling the guide jig with an alignment guide for aligning the guide jig in a desired medial to lateral orientation with respect to the knee joint;

and wherein the body is adapted for aligning the guide jig at a desired angle in an anterior to posterior direction of the knee joint and for securing of the guide jig at the desired angle prior to removal of the body from about the knee joint for allowing cutting of the one or both of the tibia and the femur to be guided by the guide jig.

59. An alignment device according to claim 58 wherein the body is adapted for aligning the guide jig at a downward said angle in the anterior to posterior direction.

60. An alignment device according to claim 58 or 59 wherein the body is adapted for being coupled with the guide jig for aligning the guide jig in position about the knee joint.

61. An alignment device according to any one of claims 58 to 60 wherein the body is adapted for being arranged between the guide jig and the alignment guide for enabling the alignment guide and the body to be removed from about the knee joint while the guide jig remains behind in position about the knee joint.

62. An alignment device according to any one of claims 58 to 60 wherein the body incorporates a first tongue for being received by the guide jig and facilitating the alignment for the guide jig in the anterior to posterior direction.

63. An alignment device according to claim 62 wherein the first tongue is arranged for projecting toward the knee joint when the body is received by the guide jig and the guide jig is secured about the knee at the desired angle.

64. An alignment according to claim 62 or 63 wherein the body incorporates a second tongue for reception by the alignment guide for achieving the coupling of the body and the alignment guide, and wherein the second tongue is arranged for projecting away from the knee.

65. An alignment device according to any one of claims 58 to 64 wherein the body is further adapted for allowing reception of a selected spacer projecting from between the tibia and the femur by the guide jig while the guide jig is received by the body and aligned at the desired angle relative to the knee joint.

66. An alignment device for supporting a cutting device for resecting bone from the tibia to a desired depth to form a recess in the tibia during arthroplasty on a knee joint, and comprising:

a body for receiving a guide jig for guiding cutting of the femur and coupling the guide jig with an alignment guide for aligning the guide jig in a desired medial to lateral orientation with respect to the knee joint;

and wherein the body is adapted for aligning the guide jig at a desired angle relative to the knee joint in an anterior to posterior direction and for being secured about the knee joint in a position determined by the guide jig for supporting the cutting device following removal of the guide jig from the body.

67. An alignment device according to claim 66 wherein the body is adapted for aligning the guide jig at a downward said angle in the anterior to posterior direction of the knee.

68. An alignment device according to claim 66 or 67 wherein the body is adapted for being coupled with the guide jig for aligning the guide jig in position about the knee joint.

69. An alignment device according to any one of claims 66 to 68 wherein the body incorporates a first tongue for being received by the guide jig and facilitating the alignment of the guide jig.

70. An alignment device according to claim 69 wherein the first tongue is arranged for projecting away from the knee joint when the body is located about the knee joint.

71. An alignment device according to claim 69 or 70 wherein the body incorporates a second tongue for reception by the alignment guide for achieving the coupling of the body and the alignment guide, and wherein the first tongue overlies the second tongue.

72. A spacer for being inserted into a knee joint to provide a desired spacing of the femur from the tibia in arthroplasty on the knee joint, comprising an elongate member with a leading end region adapted for being inserted between the tibia and the femur to thereby obtain the desired spacing of the femur from the tibia and being retained in the knee joint during resection of bone to a desired depth from one or both of the tibia and the femur respectively, and an opposite end region adapted for protruding from the knee joint and coupling with a guide jig for guiding the cutting of the or each one of the tibia and the femur in the resection of the bone.

73. A spacer according to claim 72 wherein the leading end region of the spacer is adapted for retaining the spacer in the knee joint.

74. A spacer according to claim 72 wherein the leading end region of the spacer is adapted for receiving the medial or lateral condyle of the femur for thereby retaining the spacer in the knee joint.

75. A spacer according to claim 73 wherein a concave trough is defined in the leading end region of the spacer for receiving the medial or lateral condyle of the femur and thereby retaining the spacer in the knee joint.

76. A spacer according to claim 75 wherein a raised ridge orientated in a direction across the spacer is defined on the leading end region, and the leading end region is scooped forward of the ridge thereby defining the concave trough for reception of the medial or lateral condyle of the femur.

77. A spacer according to any one of claims 72 to 76 wherein the leading end region of the spacer has an upperside and an opposite underside, and a protuberance for being seated on an articulating surface of the tibia is defined on the underside for providing the desired spacing of the femur from the tibia.

78. A spacer according to claim 77 wherein the protuberance is a bulbous protuberance for being seated on a low region of the tibia under the medial or lateral condyle of the femur.

79. A set of spacers for allowing selection of at least one of the spacers for insertion into a knee joint to provide a desired spacing of the femur from the tibia in arthroplasty on the knee joint, each said spacer respectively comprising an elongate member with a leading end region adapted for being inserted between the tibia and the femur to thereby space the femur from the tibia and being retained in the knee joint during resection of bone from one or both of the tibia and the femur respectively, and an opposite end region adapted for protruding from the knee joint and coupling with a guide jig for guiding cutting of the or each one of the tibia and the femur in the resection of the bone, wherein the spacers have a different thickness to one another for providing different spacings of the femur from the tibia.

80. A set of spacers according to claim 79 wherein the leading end region of each said spacer is adapted for retaining the spacer in the knee joint, respectively.

81. A set of spacers according to claim 79 wherein the leading end region of each said spacer is adapted for receiving the medial or lateral condyle of the femur and thereby retaining the spacer in the knee joint, respectively.

82. A set of spacers according to any one of claims 79 to 82 wherein the leading end region of each said spacer has an upperside and an opposite underside, and a protuberance for being seated on an articulating surface of the tibia is defined on the underside of each for spacing the femur from the tibia.

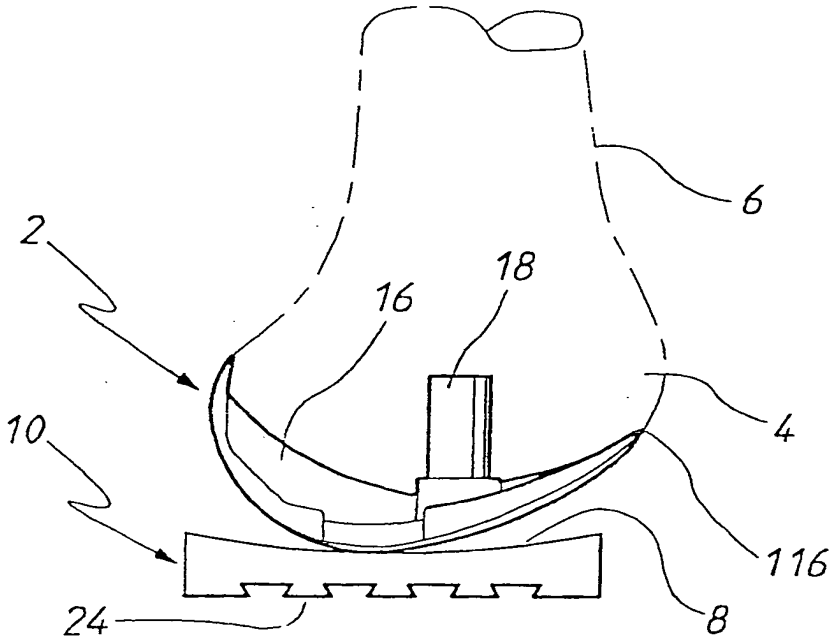


FIG. 1

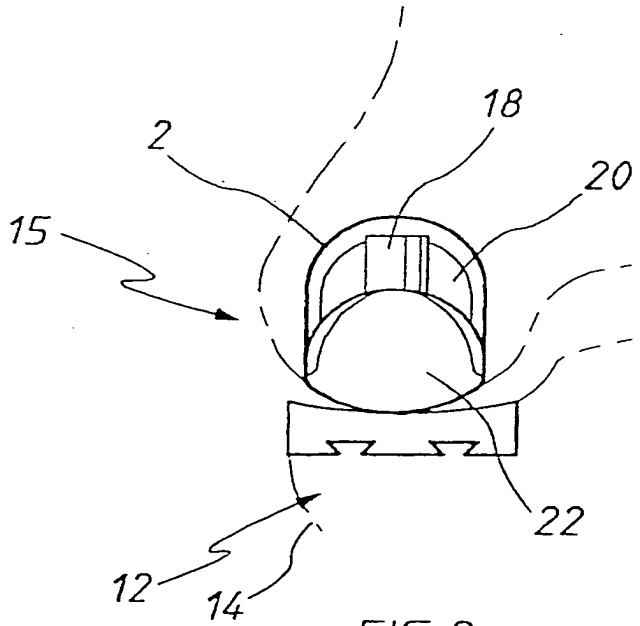


FIG. 2

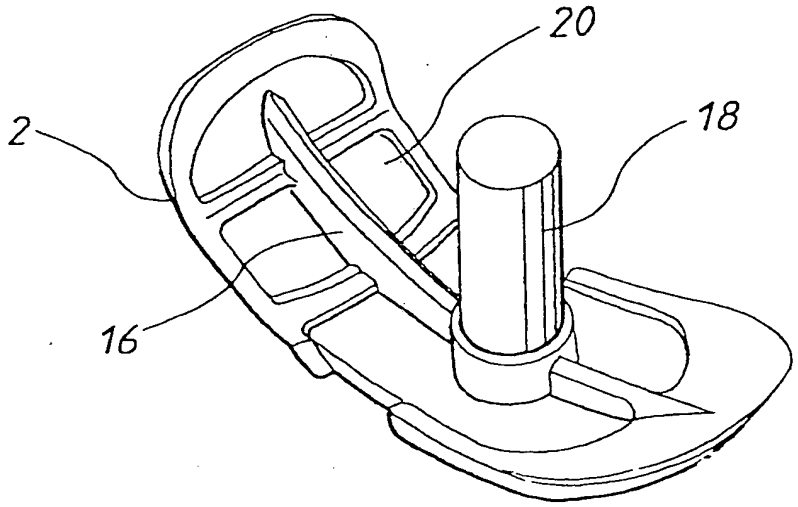


FIG.3

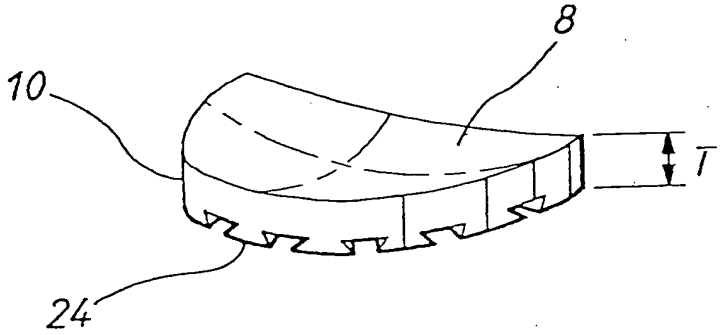


FIG.4

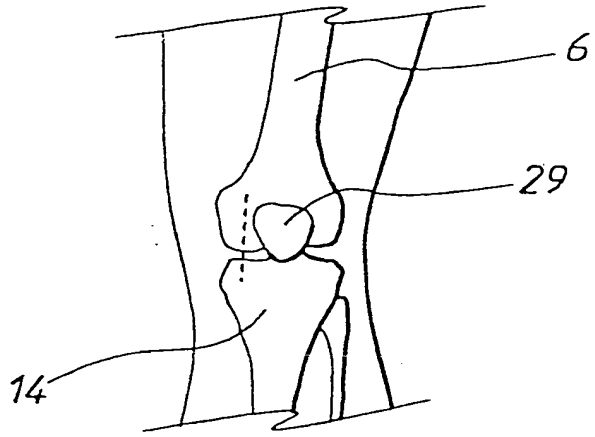


FIG.5

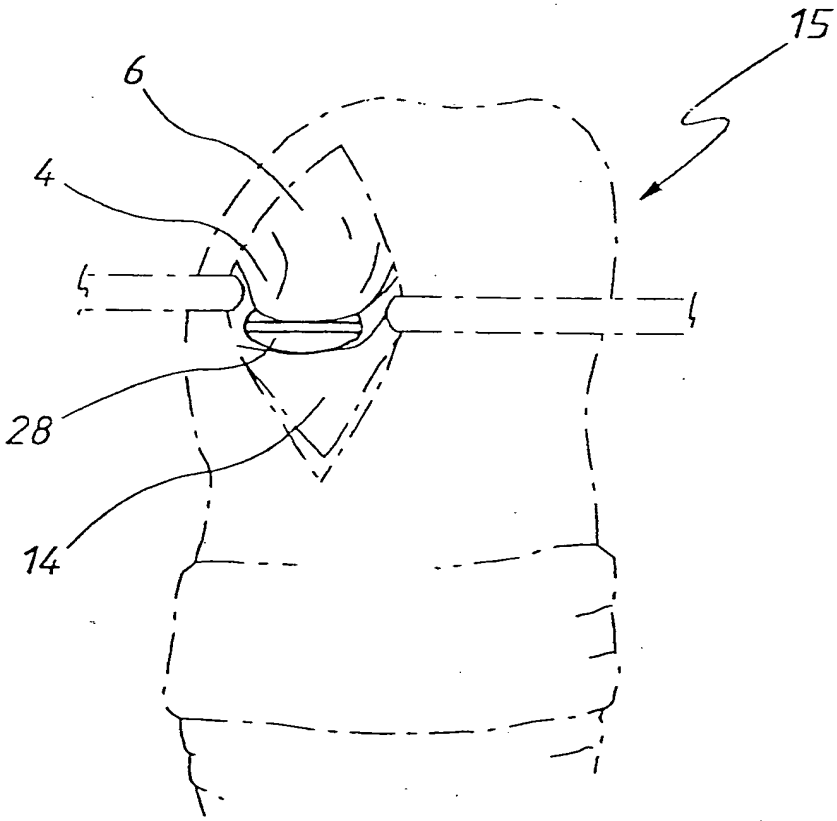


FIG.6

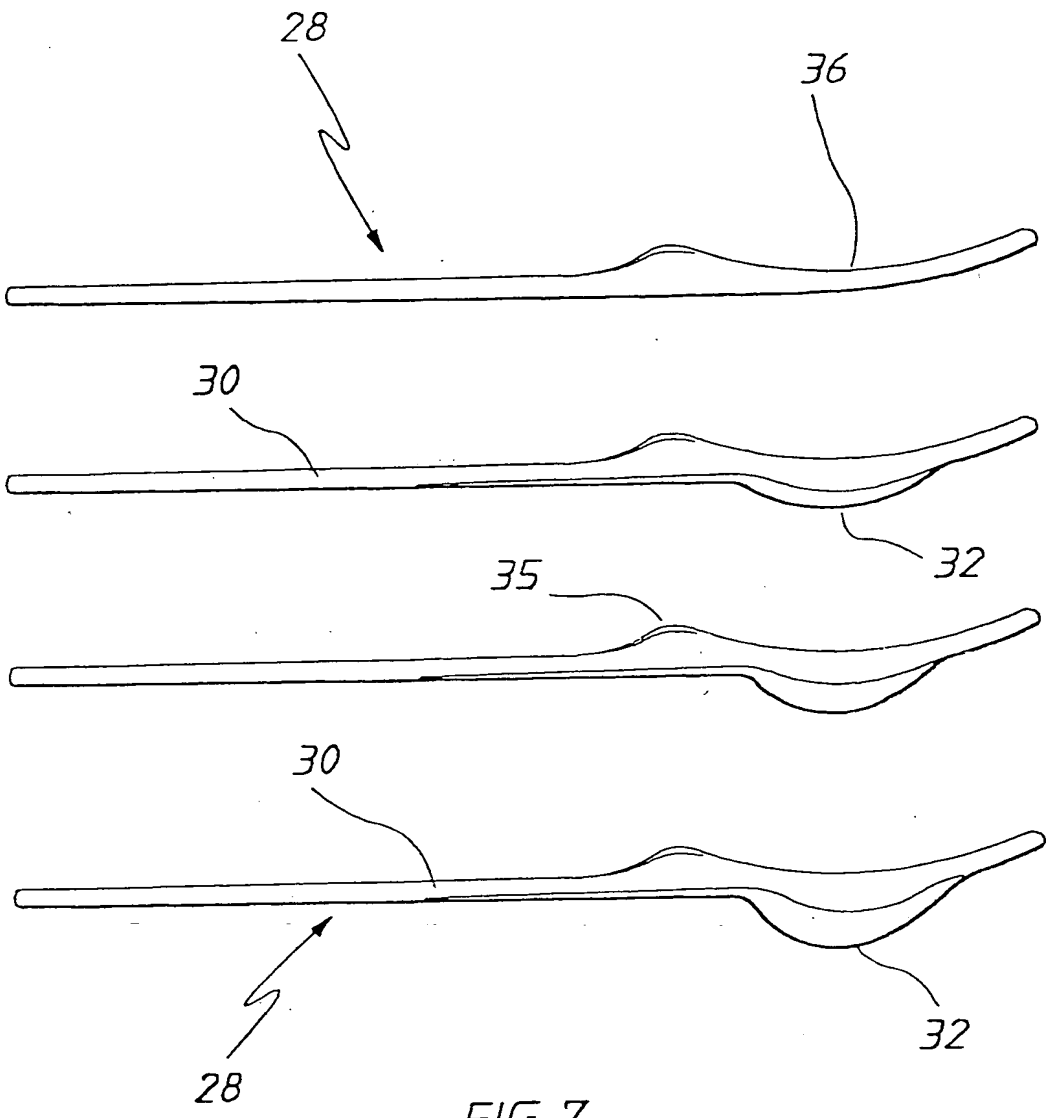


FIG.7

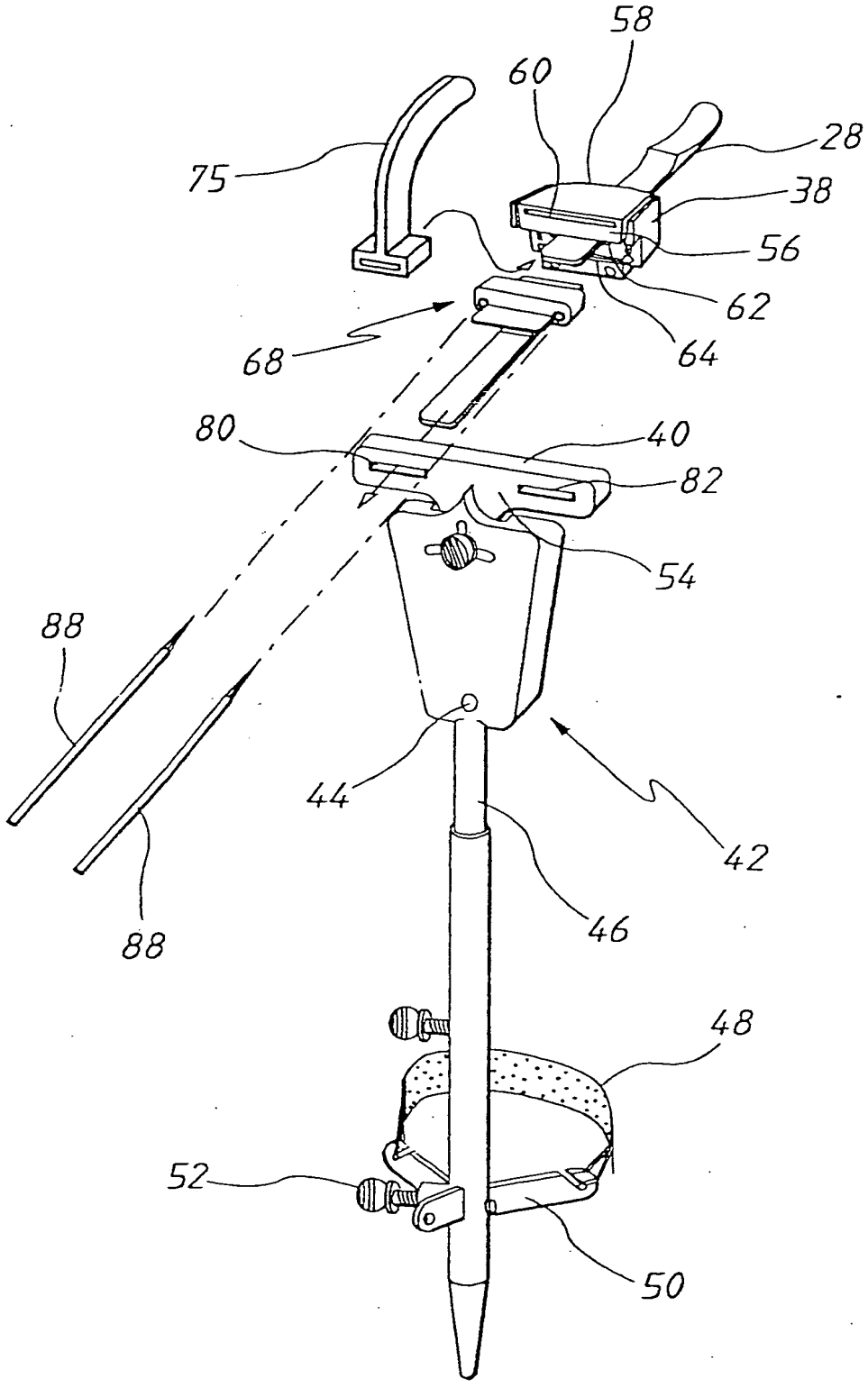


FIG.8

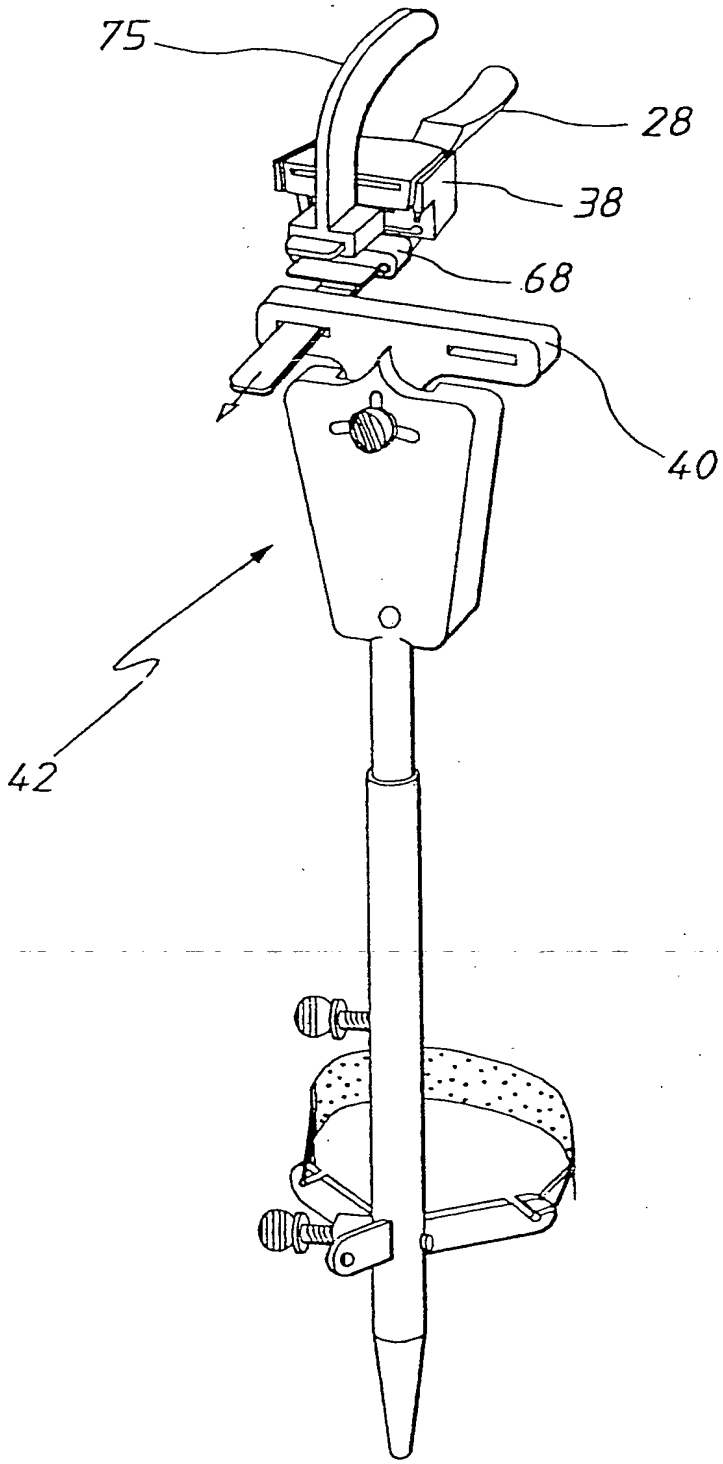


FIG. 9a

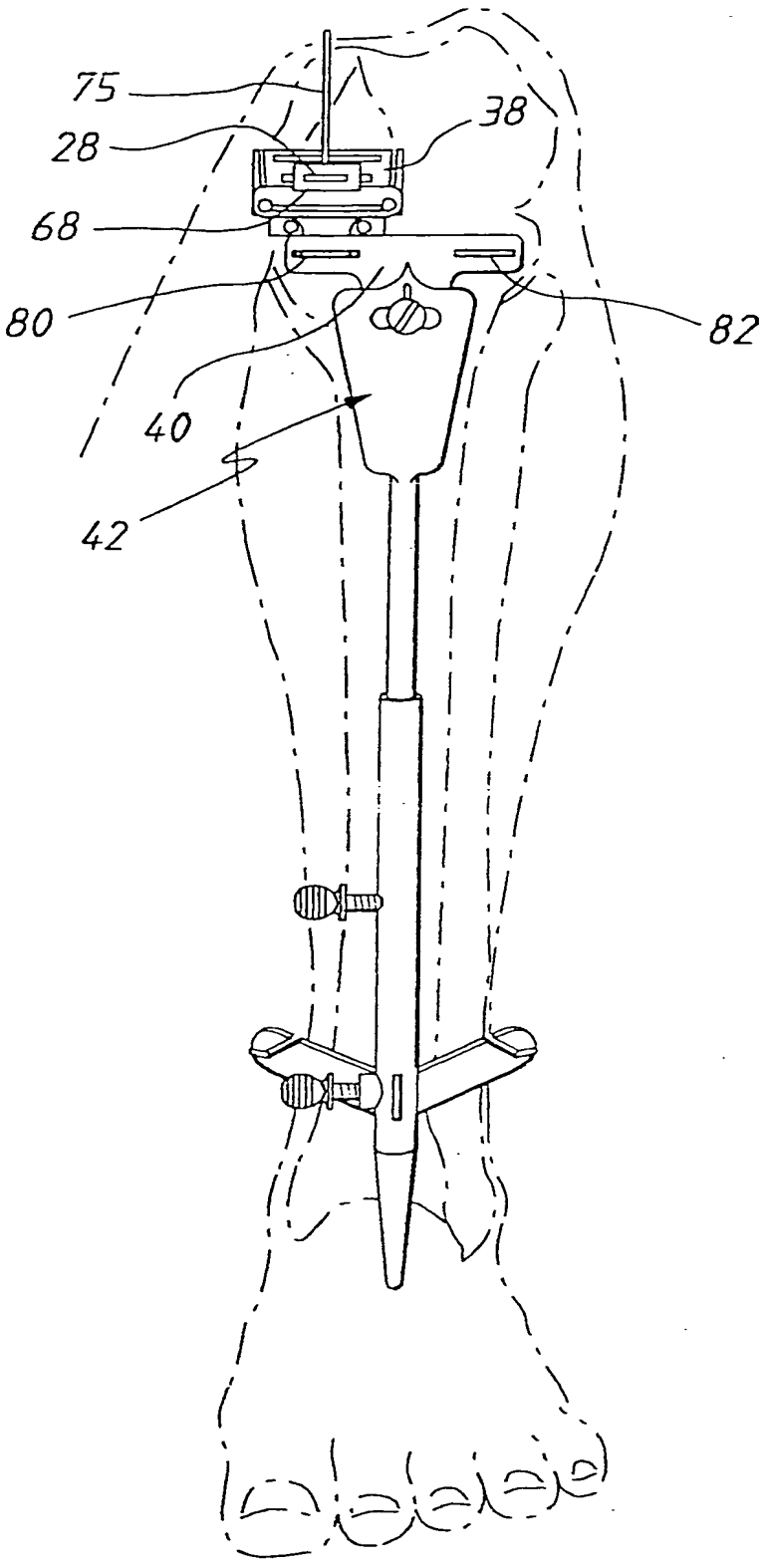


FIG. 9b

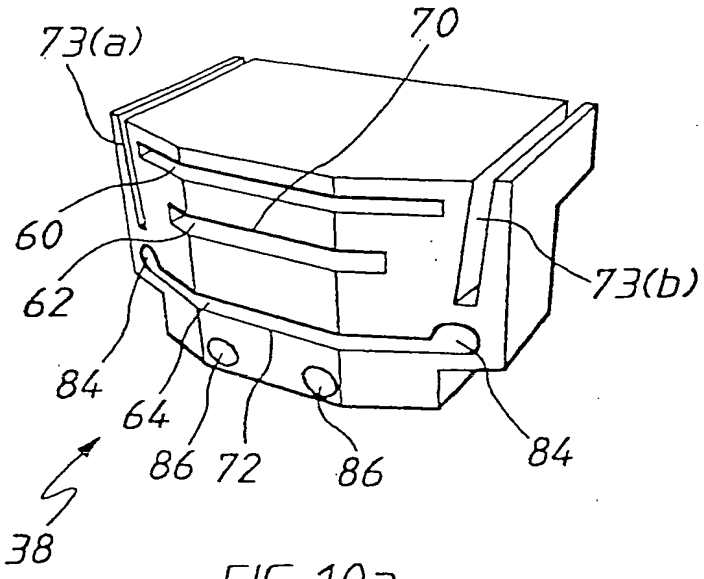


FIG. 10a

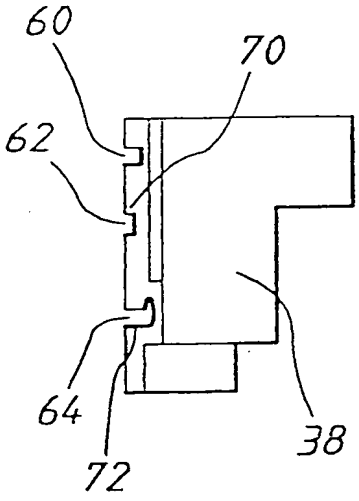


FIG. 10b

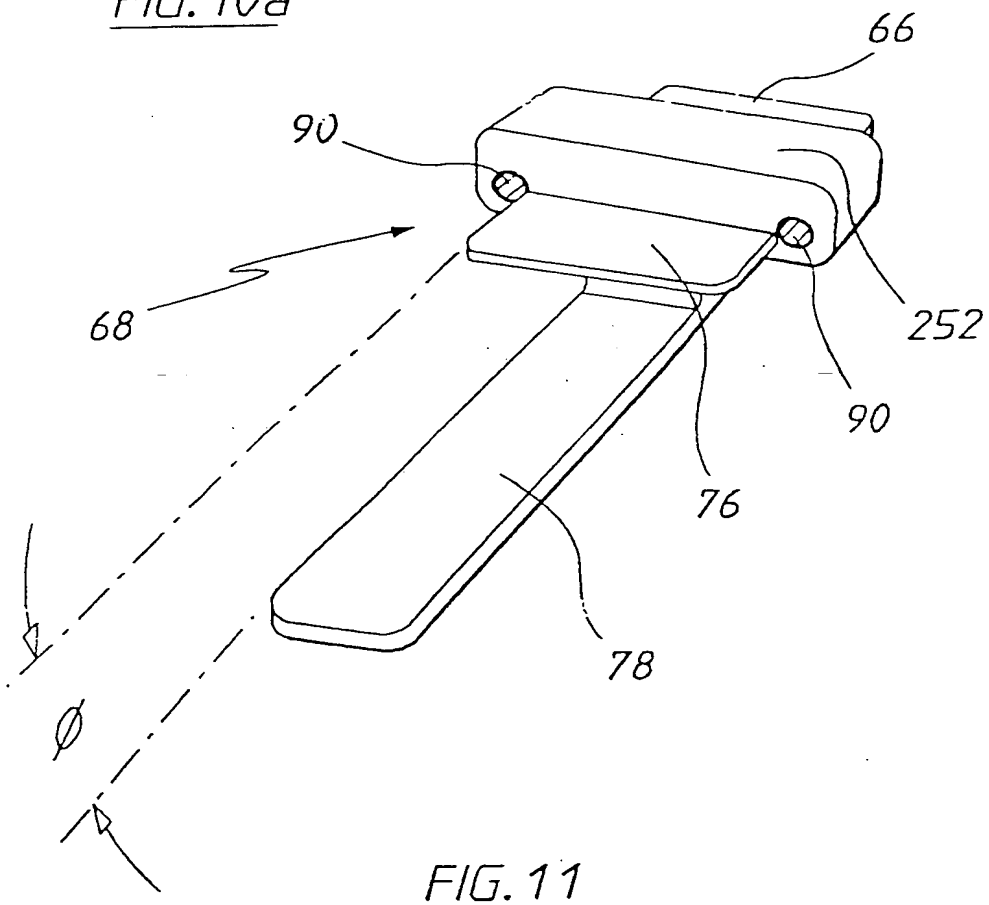


FIG. 11

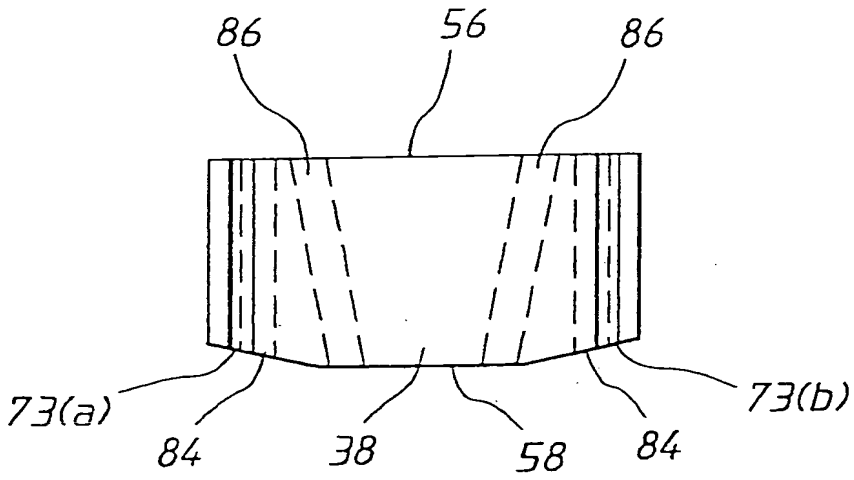


FIG. 12

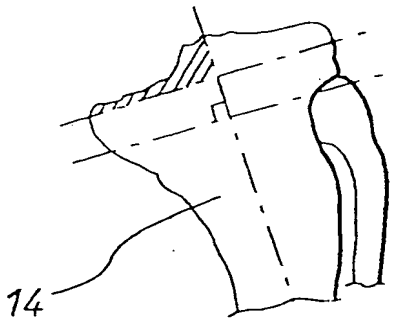


FIG. 13

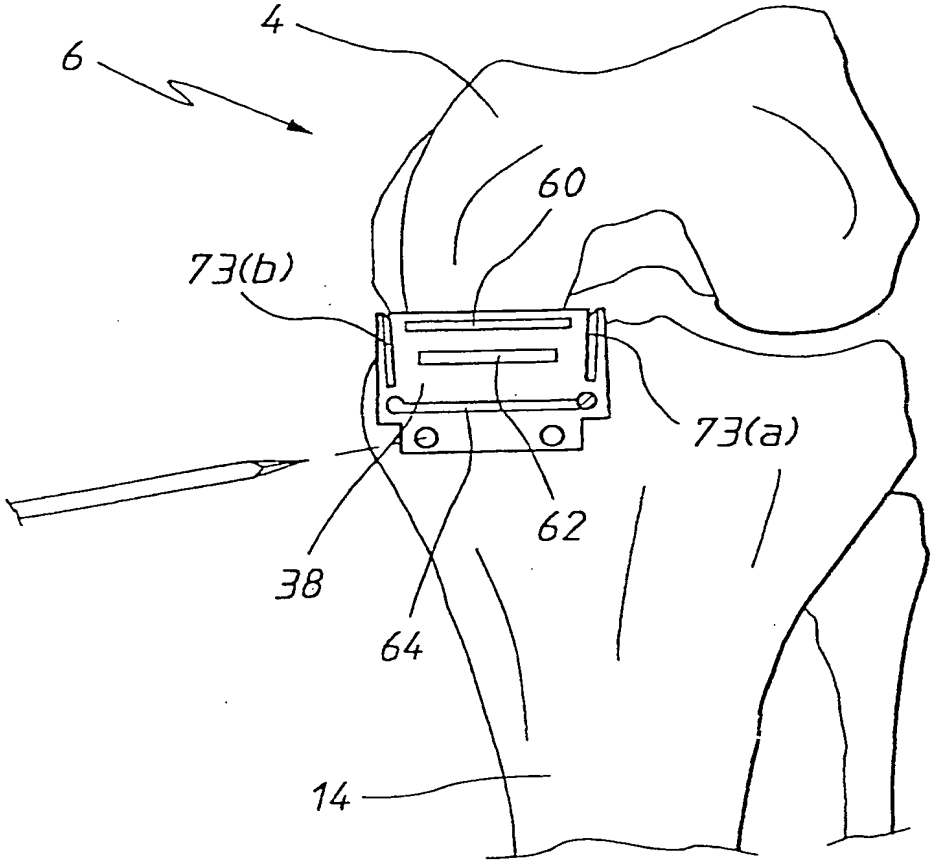


FIG. 14

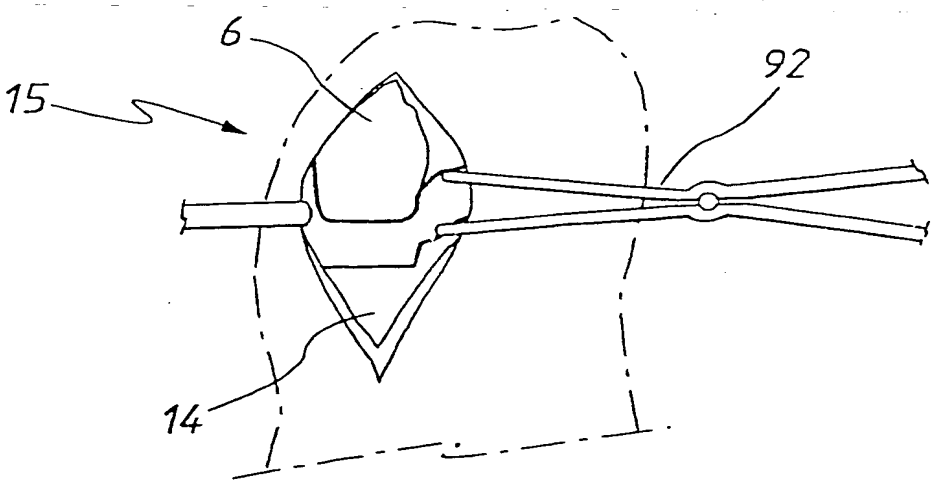


FIG. 15

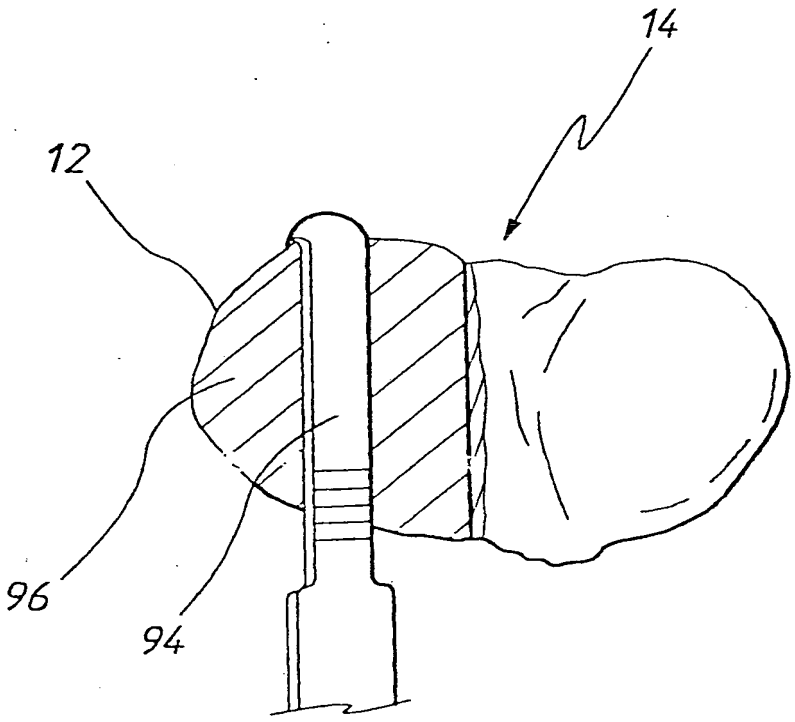


FIG. 16

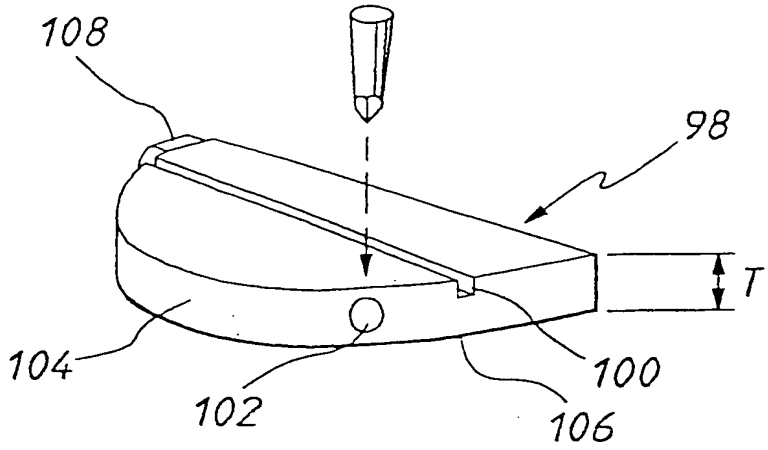


FIG. 17

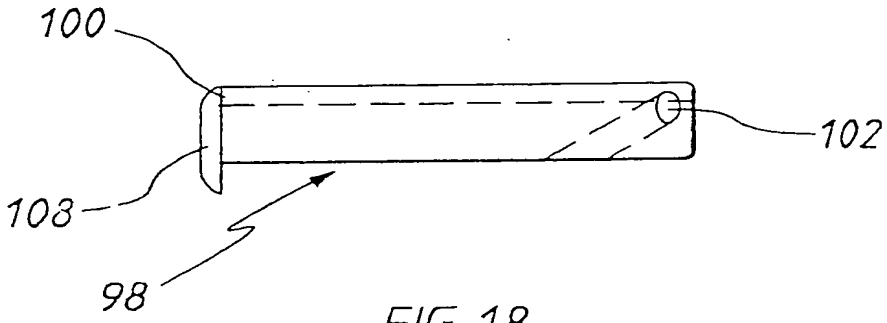


FIG. 18

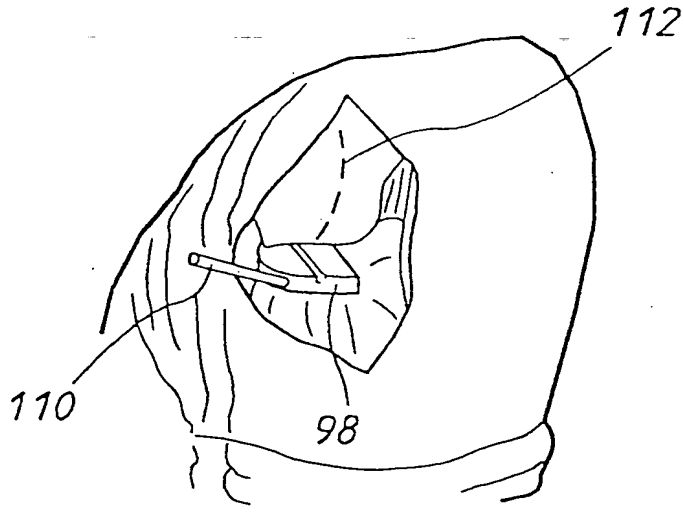


FIG. 19

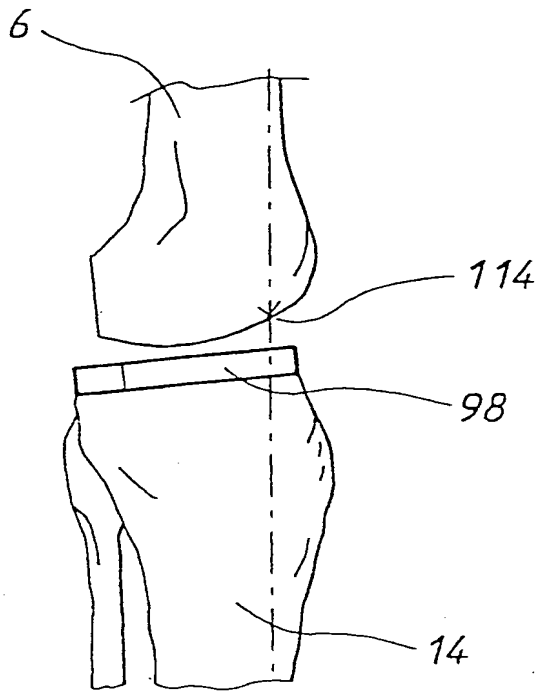


FIG.20

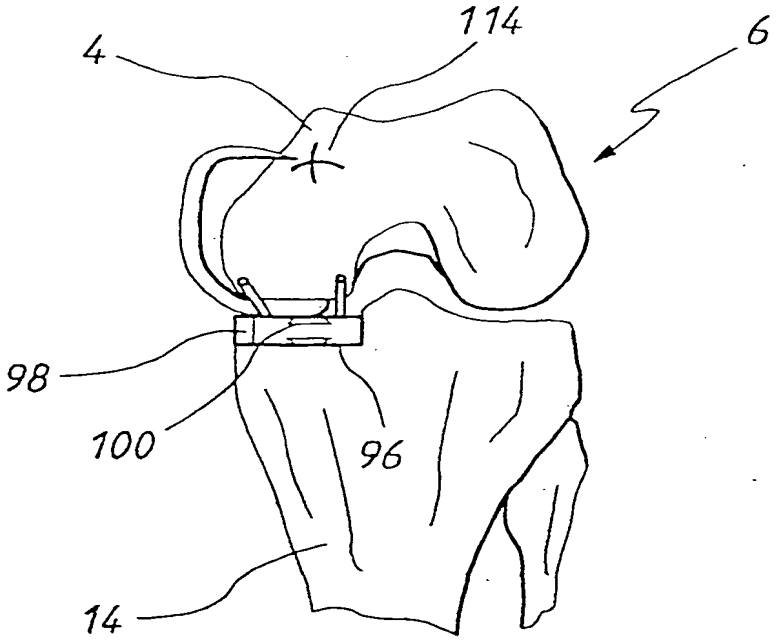


FIG.21

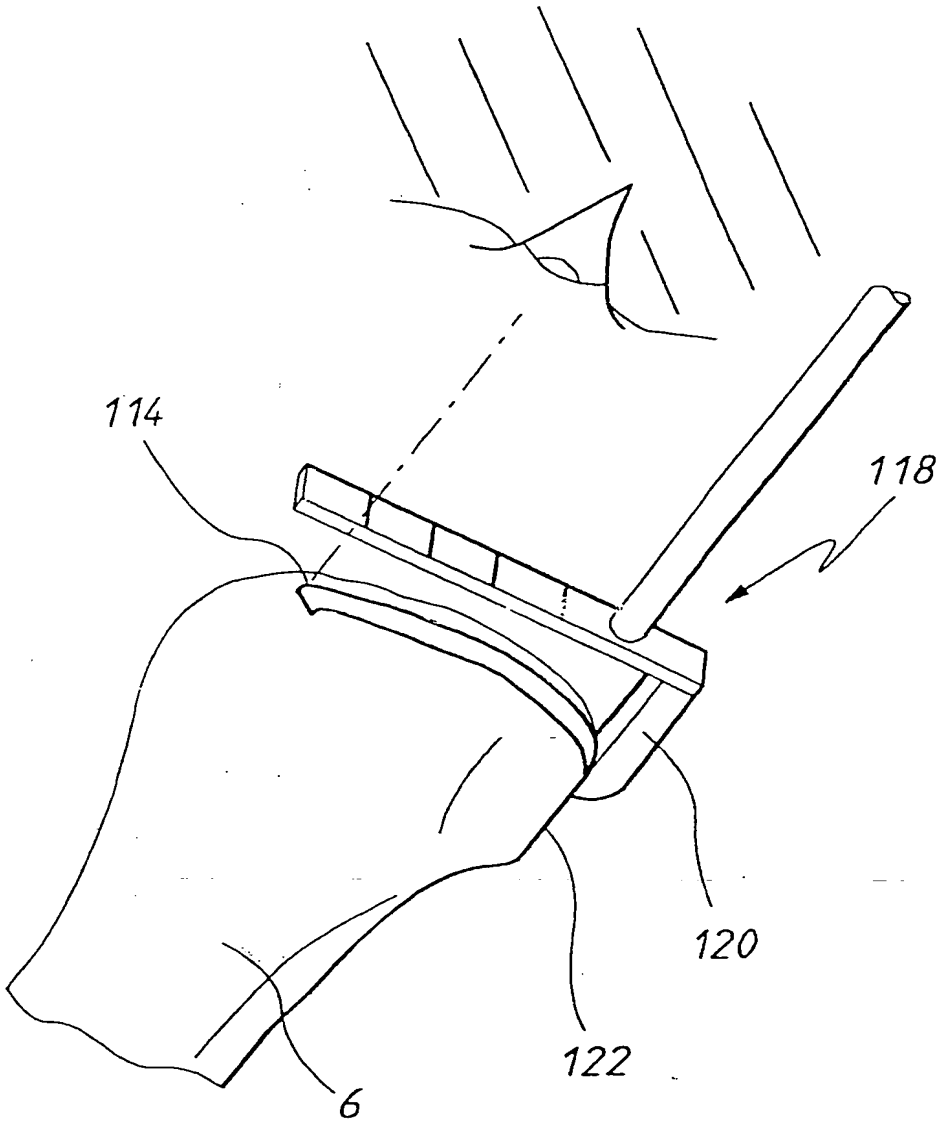


FIG.22

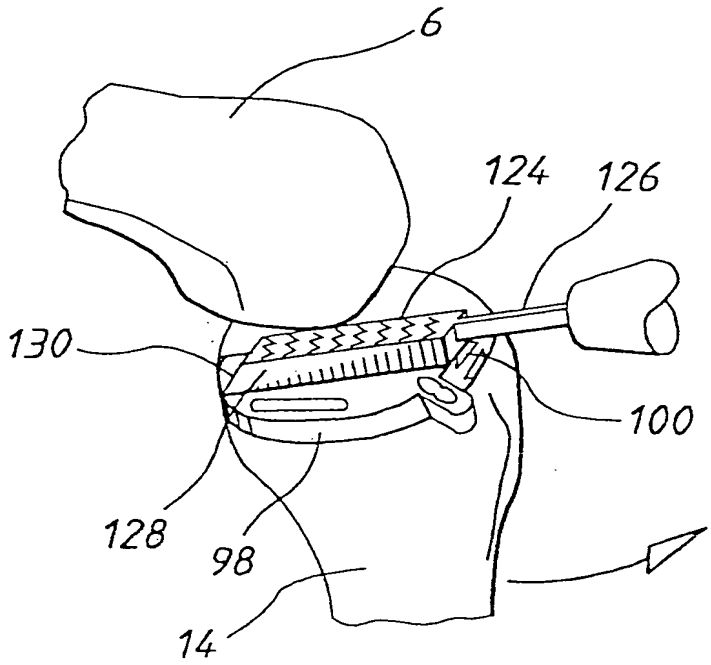


FIG.23

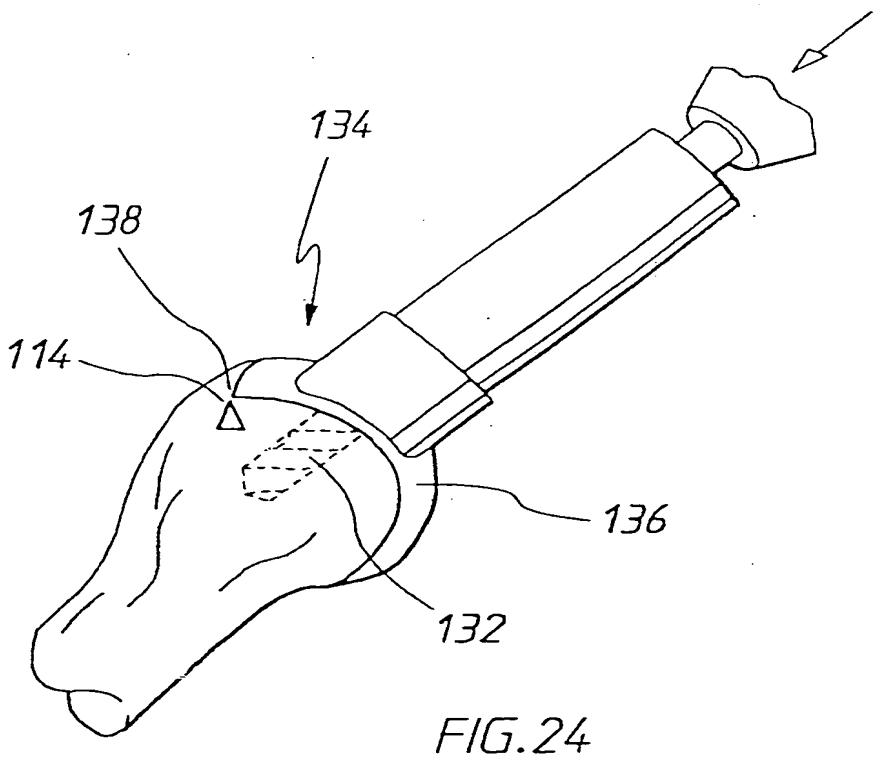


FIG.24

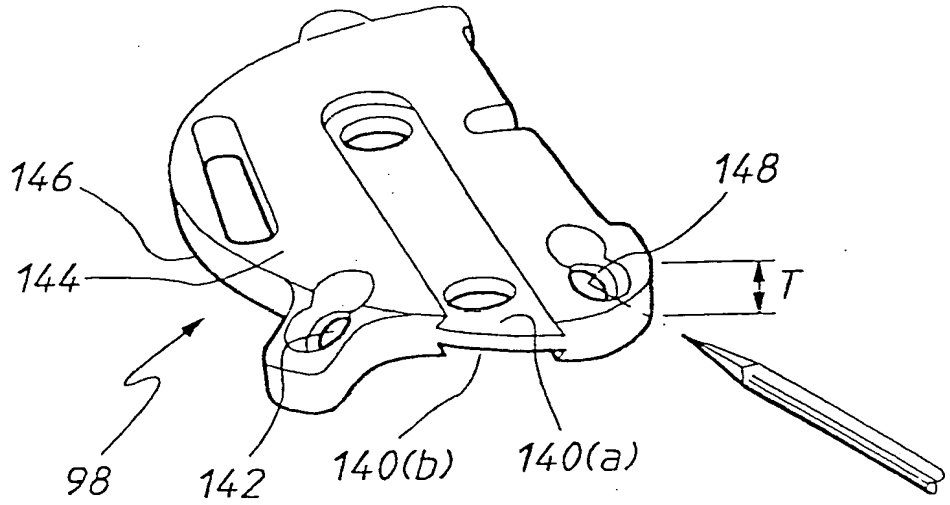


FIG.25

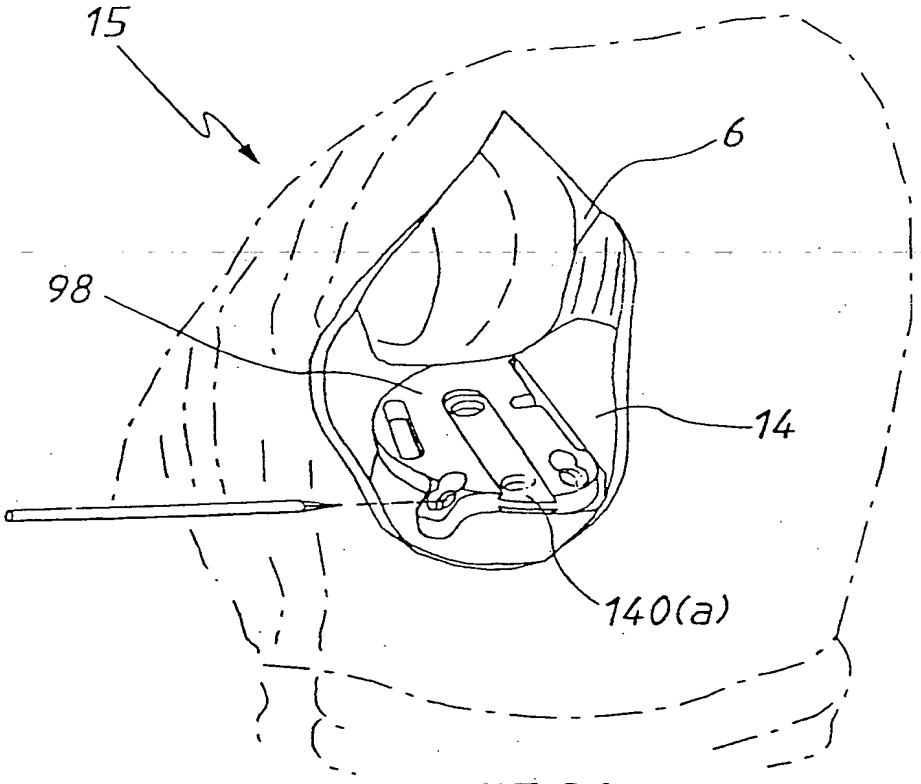


FIG.26

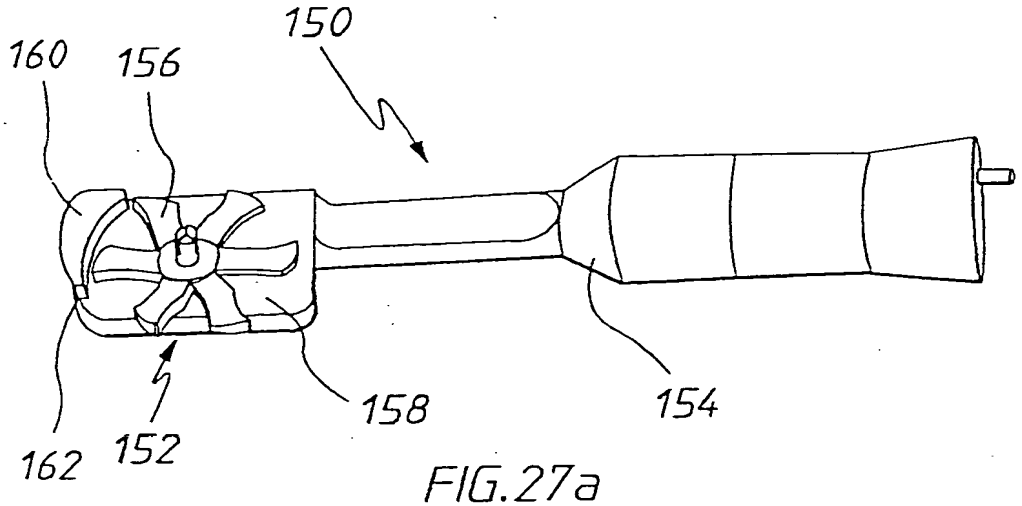


FIG.27a

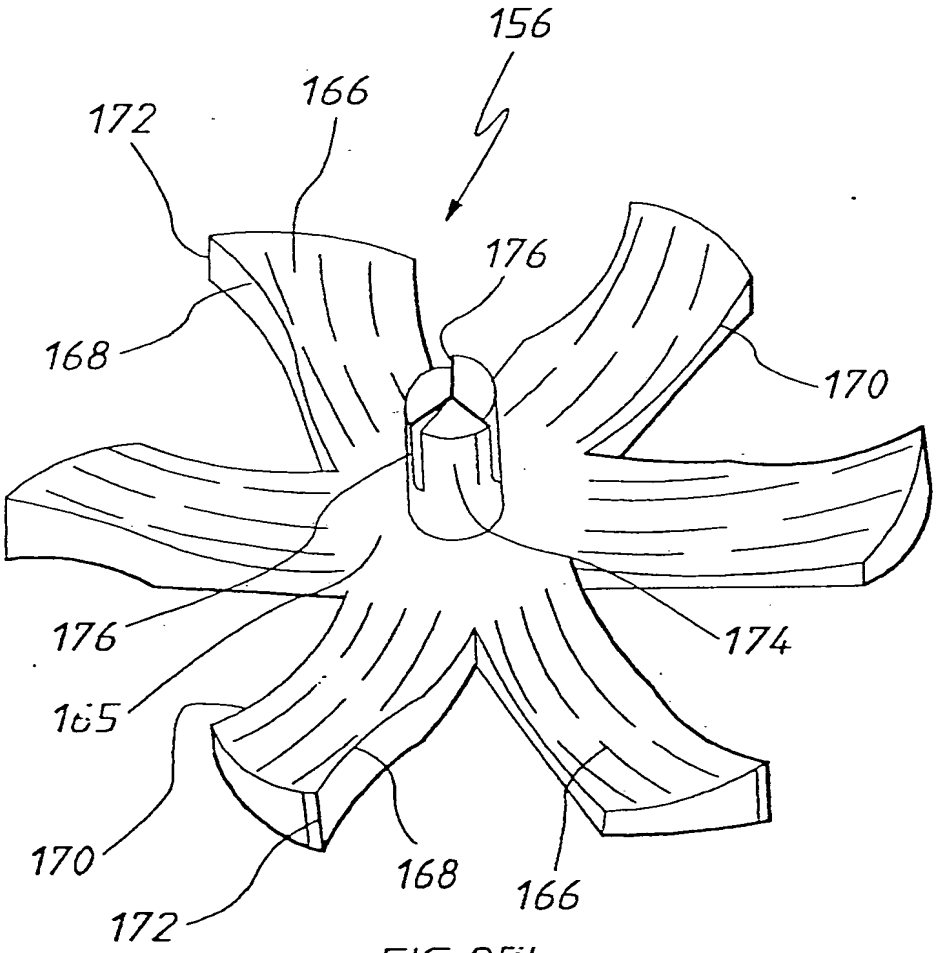


FIG.27b

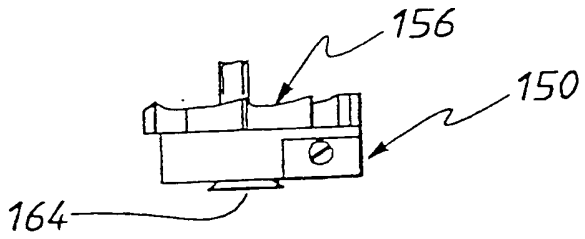


FIG.28

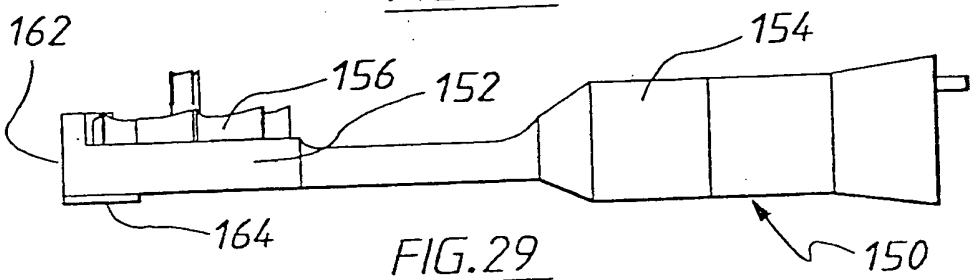


FIG.29

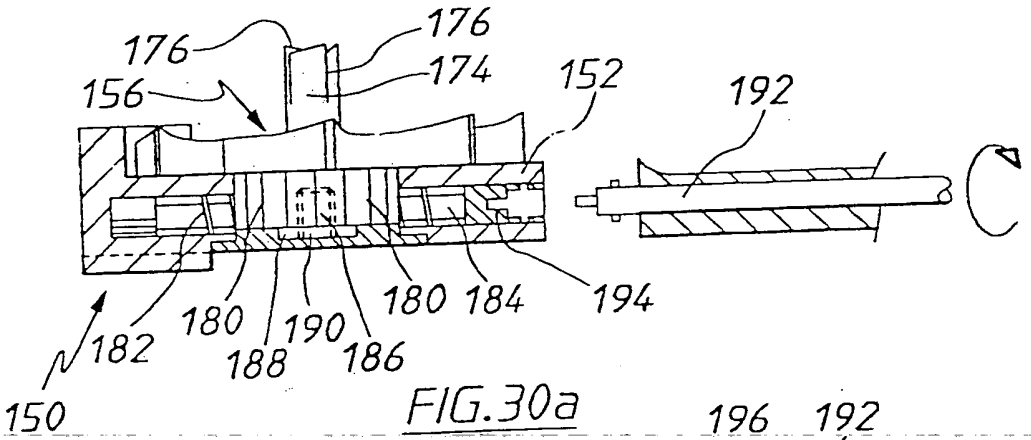


FIG.30a

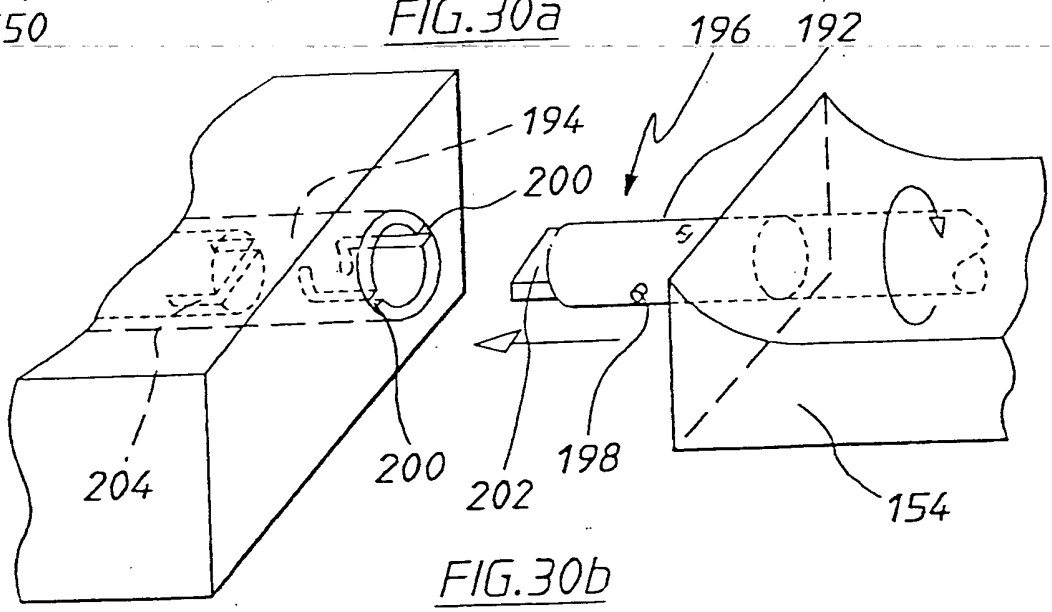


FIG.30b

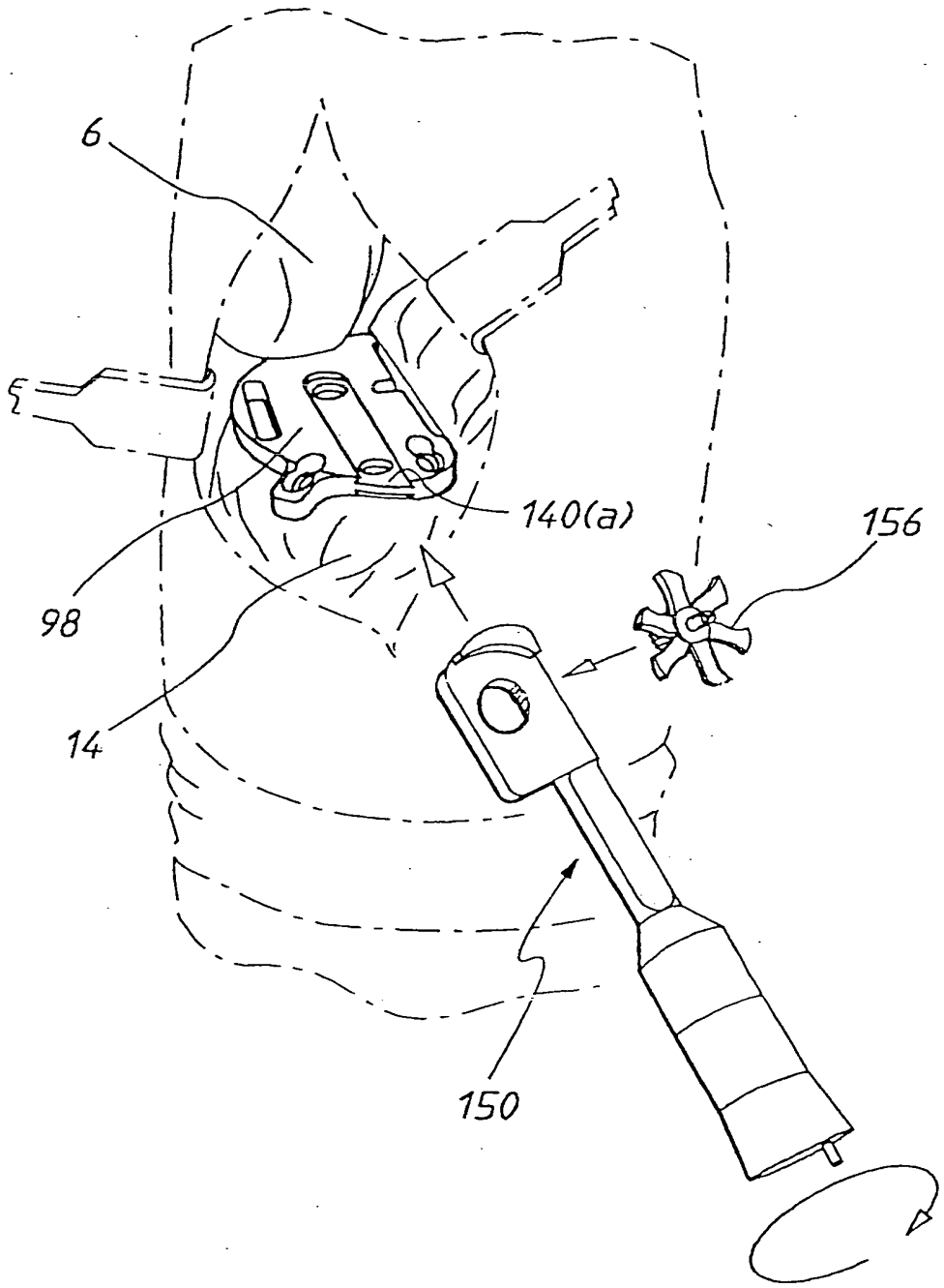


FIG.31

Substitute Sheet
(Rule 26) RO/AU

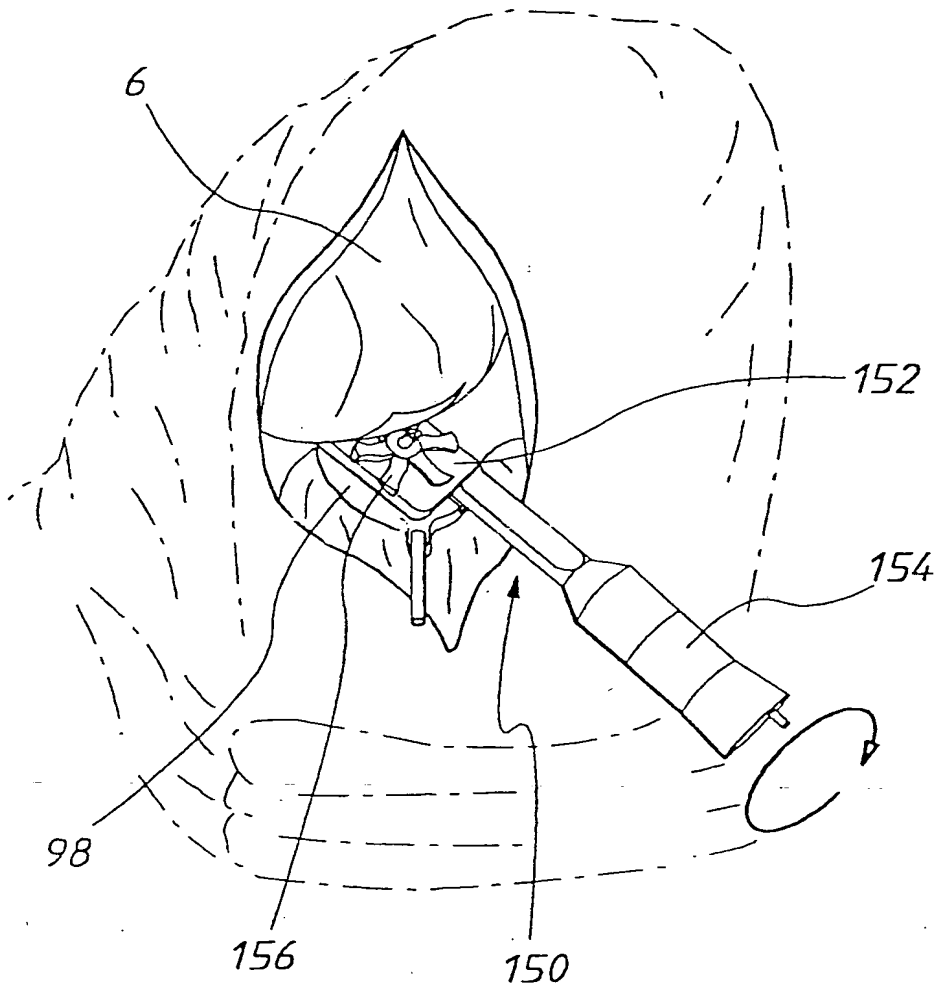


FIG.32

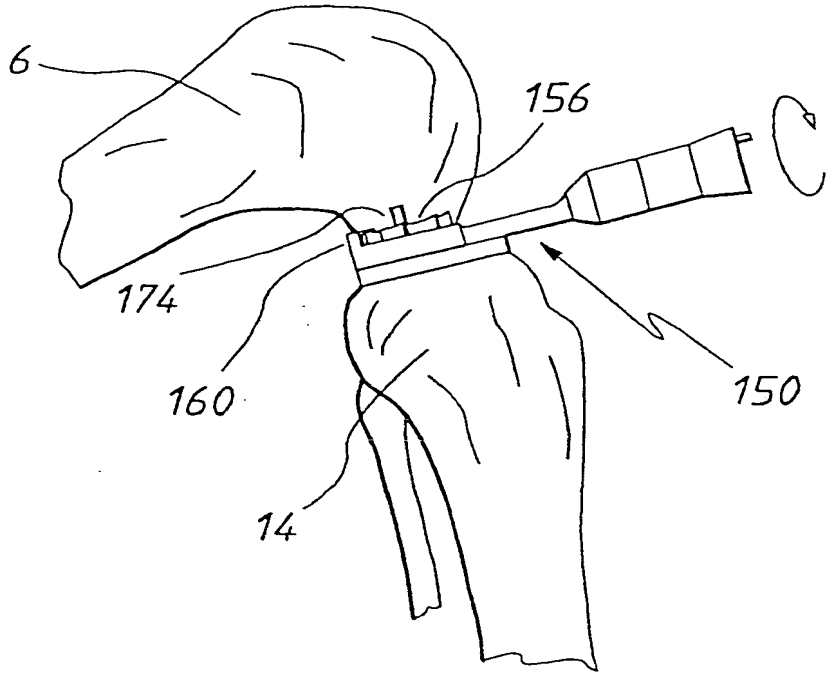


FIG.33a

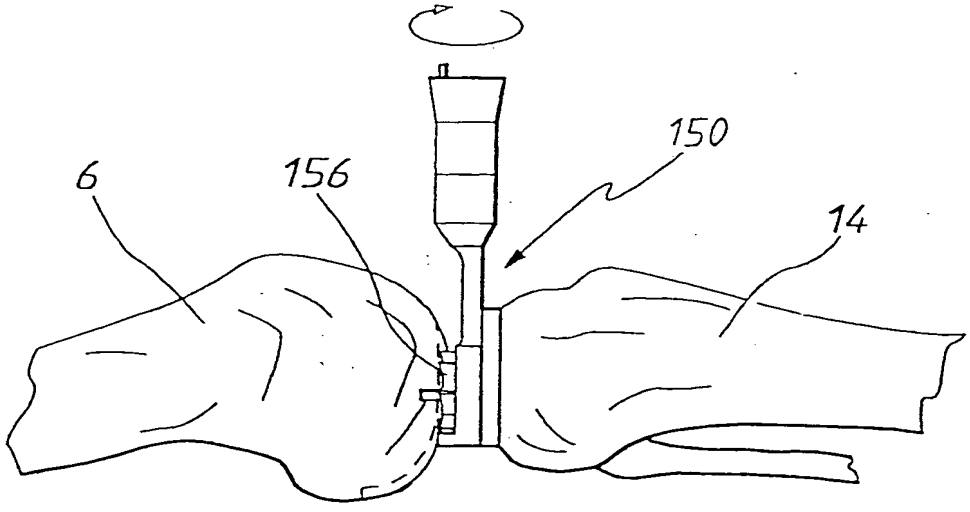


FIG.33b

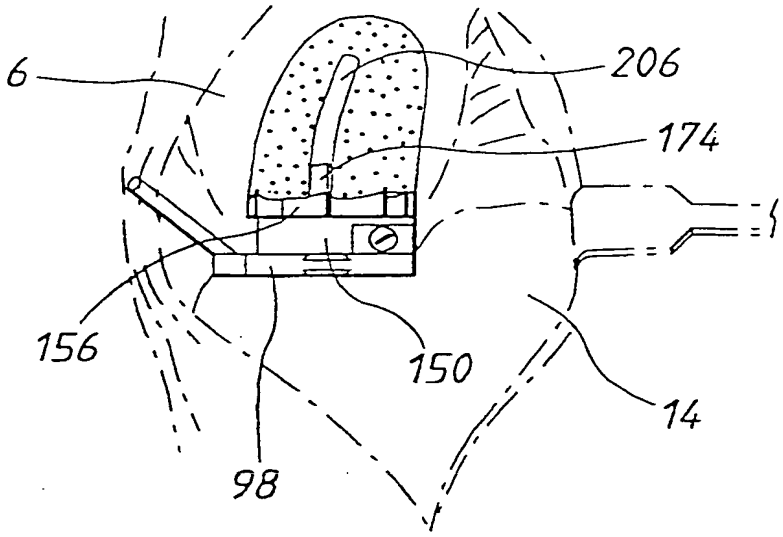


FIG.33c

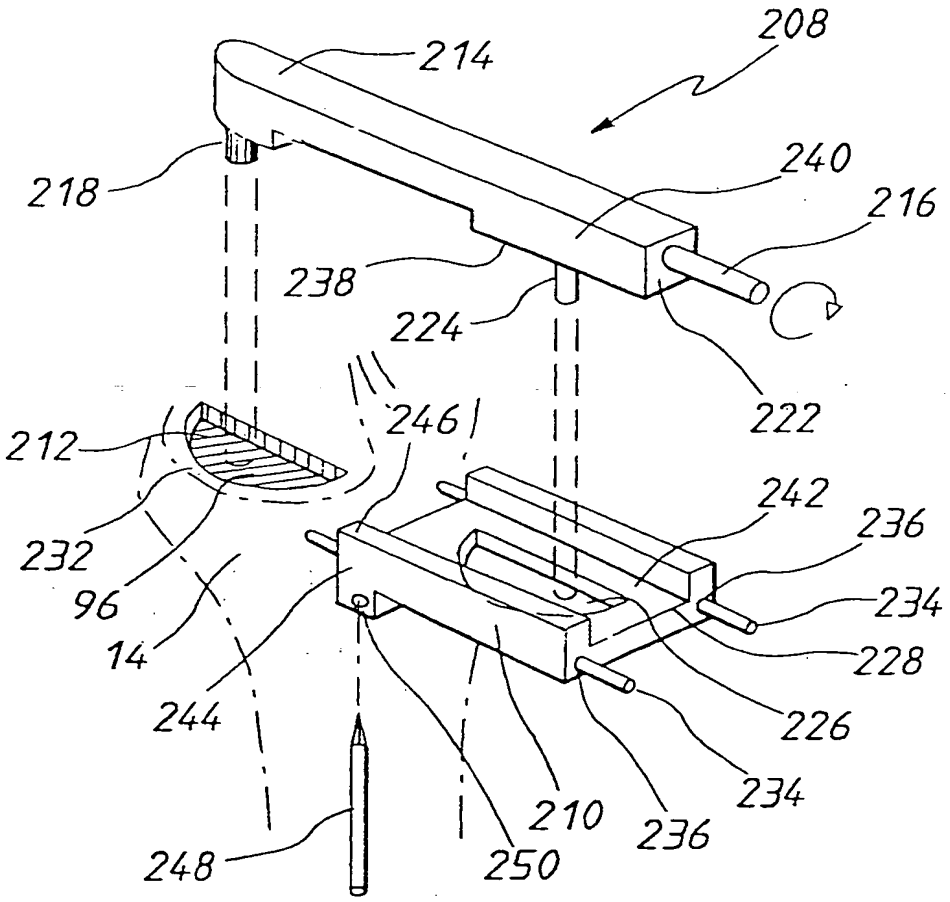


FIG.34

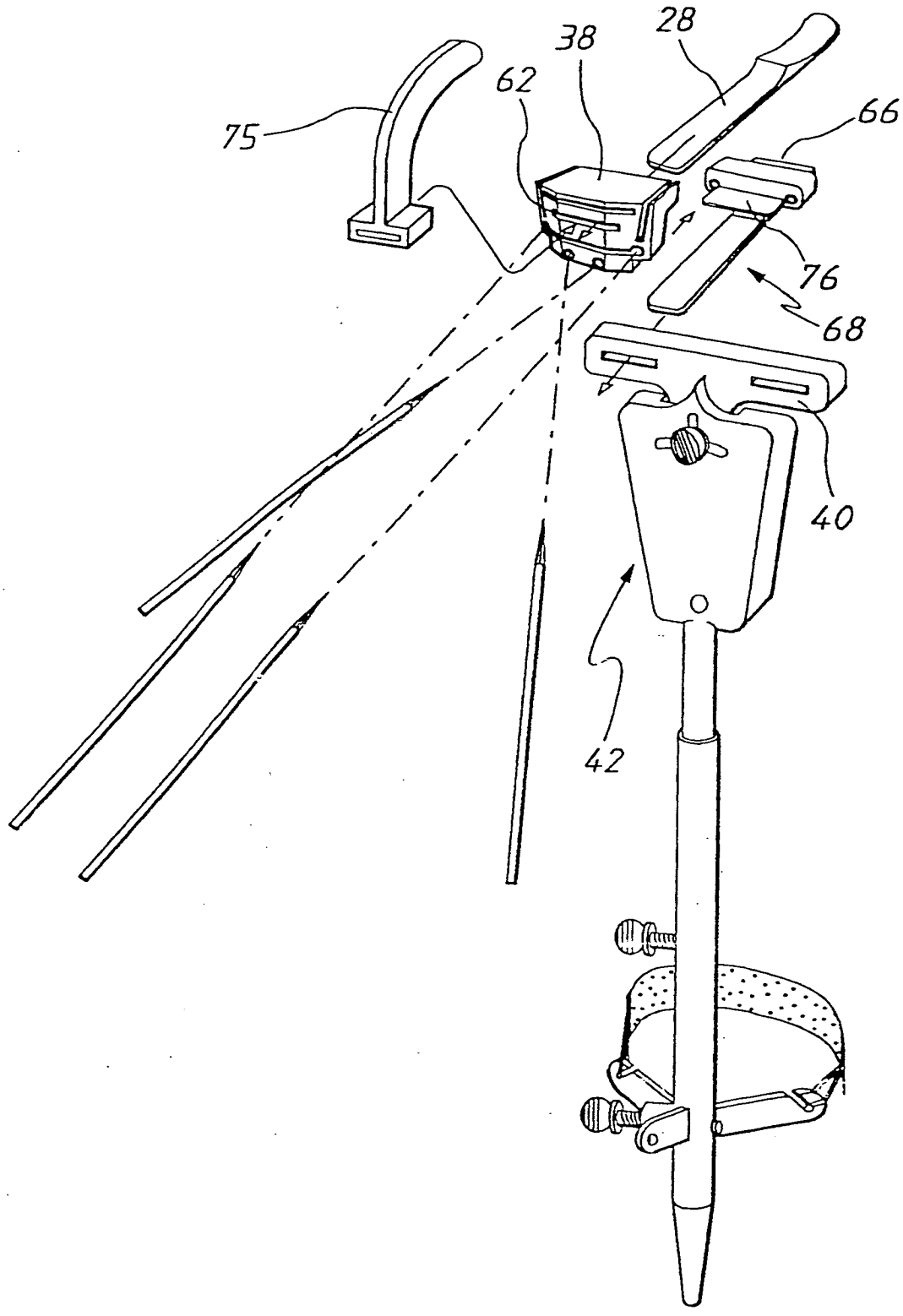


FIG.35

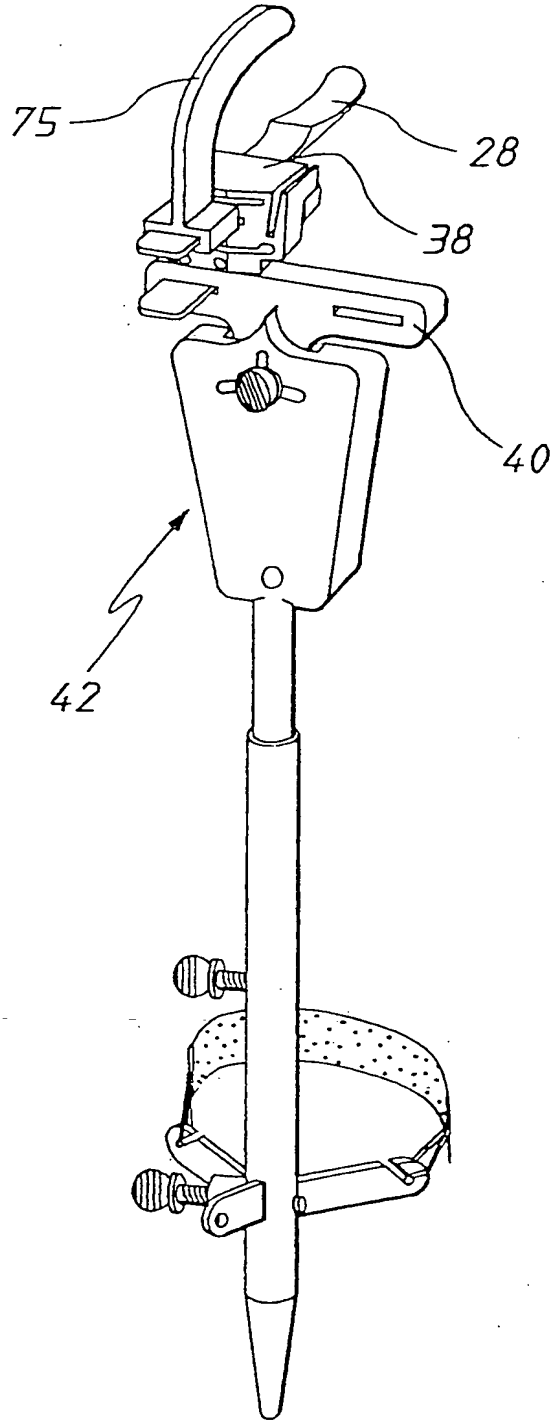


FIG. 36

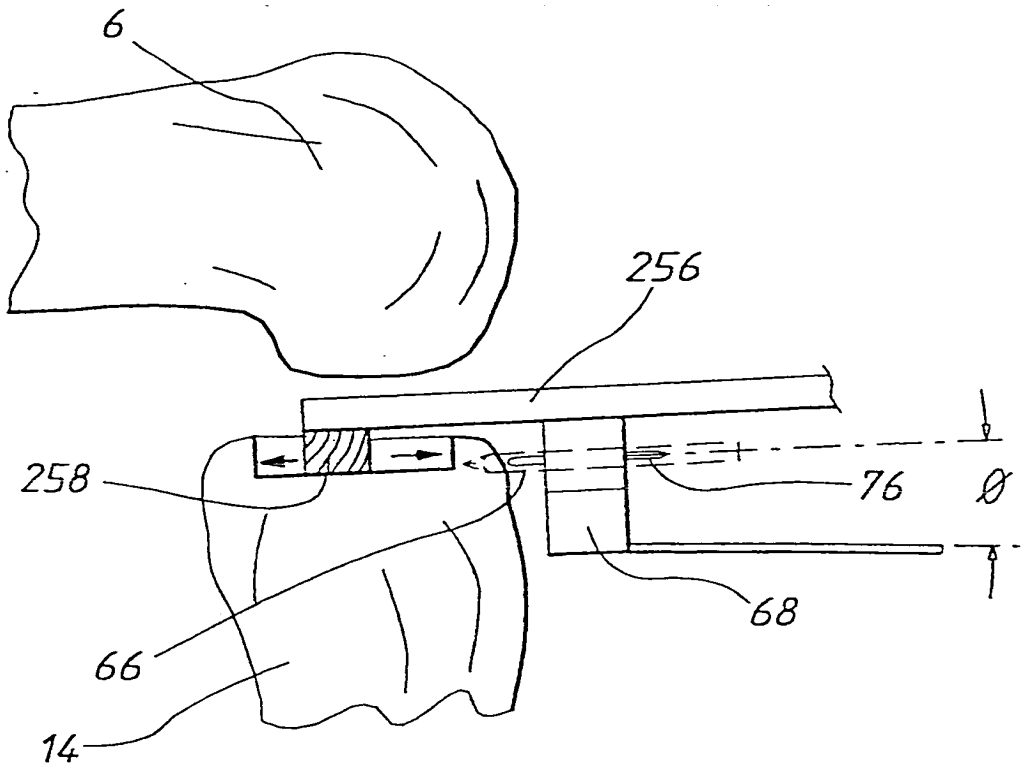


FIG.37

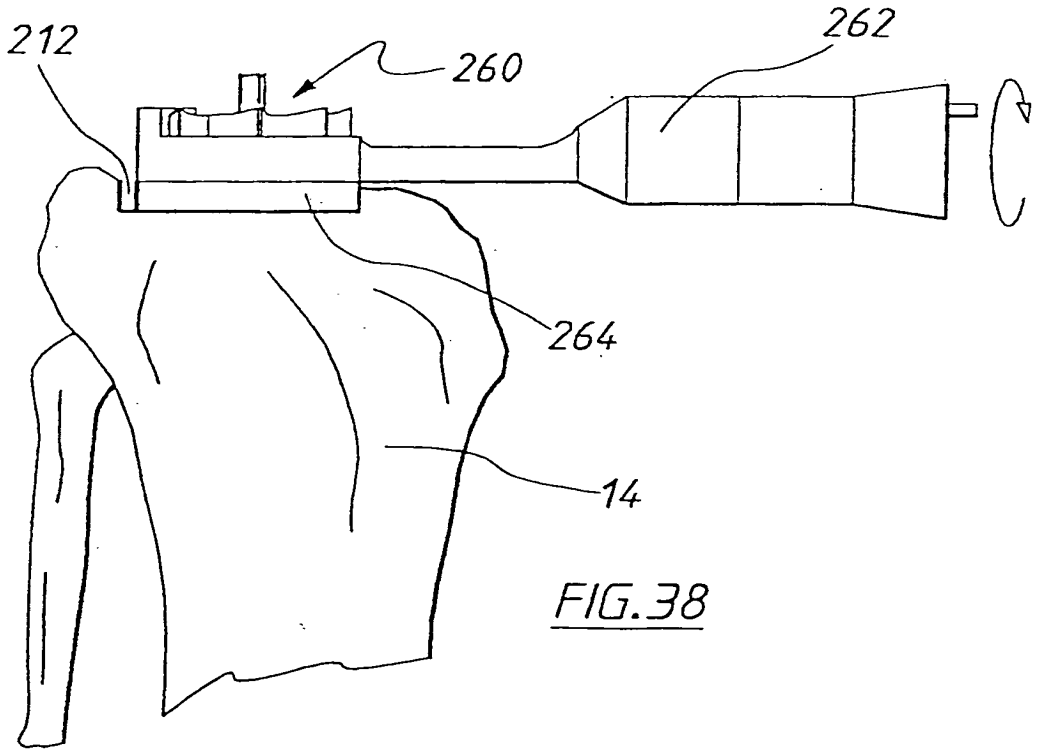


FIG.38

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU01/00258

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. [7]: A61B 17/14, 17/15, 17/56, 17/90

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
REFER ELECTRONIC DATABASE CONSULTED BELOW

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
DWPI & keywords: knee, tibia, femur, femoral, arthroplasty, replacement, prosthes:, implant, reconstruct, distance, gap, spac:, cut, mill, resect, guid:, jig, template

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5735904 A (PAPPAS) 7 April 1998 Whole document	1 to 26 34 to 57 72 to 82
X	US 6013081 A (BURKINSHAW et al) 11 January 2000 Whole document	58 to 71
X	EP 857463 A2 (HOWMEDICA, INC) 12 August 1998 Whole document	58 to 71

[X] Further documents are listed in the continuation of Box C [X] See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
17 May 2001	24 MAY 2001
Name and mailing address of the ISA/AU	Authorized officer
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	COLIN FITZGIBBON Telephone No : (02) 6283 2226

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU01/00258

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5830216 A (INSALL et al) 3 November 1998 Whole document	58 to 71
A	US 5122144 A (BERT et al) 16 June 1992	
A	US 4825857 A (KENNA) 2 May 1989	

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU01/00258

Box I **Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos :

because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos :

because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos :

because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box II **Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

See separate sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims

2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant. this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently. this international search report is restricted to the invention first mentioned in the claims: it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU01/00258

Supplemental Box
(To be used when the space in any of Boxes I to VIII is not sufficient)

Continuation of Box No: II Lack of Unity of Invention

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are different inventions as follows:

1. Claims 1 to 26 are directed to a method of arthroplasty on a knee joint, comprising the steps of (a) obtaining a desired spacing of the femur and the tibia, (b) determining the depth of bone to be resected from at least one of the tibia and the femur on the basis of the spacing to enable fitting of at least one tibia and femoral prosthesis, (c) resecting bone to the depth determined and (d) fitting the prosthesis. It is considered that determining the desired spacing prior to resecting comprises a first "special technical feature".

2. Claims 27 to 33 are directed to a method of arthoplasty comprising the steps of (a) locating a cutting device in a knee joint between the femur and the tibia and (b) moving the tibia through an arc of motion about the femur between backward and forward positions while the cutting device is operating to remove bone substantially to a desired depth from the femur, for enabling the fitting of a femoral prosthesis. It is considered that moving the tibia through an arc of motion about the femur between backward and forward positions while the cutting device is operating comprises a second "special technical feature".

3. Claims 34 to 57 are directed to a method of determining the position of a guide jig about a knee joint about a knee joint, the method comprising (a) locating a selected spacer in the knee joint to obtain a desired spacing of the femur from the tibia and (b) arranging the guide jig and the spacer together to determine the position of the jig about the knee joint for guiding the cutting of the tibia and or femur. It is considered that arranging the guide jig and spacer together to determine the position of the guide jig comprises a third "special technical feature".

4. Claims 58 to 71 are directed to an alignment device for aligning a guide jig in position about a knee joint for guiding cutting of at least one of the tibia and femur, comprising a body for receiving the guide jig and coupling the guide jig with an alignment guide for aligning the jig in a desired medial to lateral orientation and wherein the body os adapted for aligning the guide jig at a desired angle in an anterior to posterior direction and securing the jig at the desired angle to allow cutting of on or both of the tibia and femur.

5. Claims 72 to 82 are directed to a spacer for being inserted into a knee joint to provide a desired spacing of the femur from the tibia, comprising an elongate member with a leading edge region adapted for being inserted between the tibia and the femur to obtain the desired spacing and being retained in the knee joint during resection, and an opposite end region adapted for protruding from the knee and coupling to with a guide jig. It is considered that the spacer as defined comprises a fifth "special technical feature".

Since the abovementioned groups of claims do not share any of the technical features identified, a "technical relationship" between the inventions, as defined in PCT rule 13.2 does not exist. Accordingly the international application does not relate to one invention or to a single inventive concept, a priori.

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/AU01/00258

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report	Patent Family Member					
US 5735904	EP	754439				
US 6013081	AU	58173/99	WO	200013594		
EP 857463	JP	10277071	US	5916219	US	6090114
	WO	200100096				
US 5830216	NONE					
US 5122144	US	5234433				
US 4825857	CA	1195201	CA	1229279	CA	1229771
	CA	1230277	CA	1233386	US	4787383
	US	4646729				

END OF ANNEX

THIS PAGE BLANK (USPTO)